

CONTRATO DE LOCAÇÃO Nº 016/2026

QUADRO RESUMO

A) PARTES

(i) Locatária:

IMED – Instituto de Medicina, Estudos e Desenvolvimento

CNPJ/MF nº 19.324.171/0004-47

Endereço: Rua 3, nº 281, Quadra 04, Lote 10, Jardim Primavera, Trindade/GO, CEP: 75.390-334.

(ii) Locadora:

Nome: Metrolab Soluções em Engenharia Clínica Ltda

CNPJ/MF nº 32.487.278/0001-21

Endereço: Rua C155, nº 789, Jardim América, Qd 365, CEP.: 74.275-150, Goiânia/GO

B) OBJETO: Locação de Lavadora Ultrassônica

C) PRAZO DE VIGÊNCIA: 12 (doze) meses contados de sua assinatura, com prorrogação automática até o fim do Contrato de Gestão firmado entre a **Locatária** e a Secretaria de Estado de Saúde de Goiás (SES/GO) ou de novo contrato de gestão que o venha suceder.

D) PRAZO DE INSTALAÇÃO DOS EQUIPAMENTOS: até 07 (sete) dias contados da assinatura do contrato

E) LOCAL DE ENTREGA/INSTALAÇÃO: Hospital Estadual de Trindade Walda Ferreira dos Santos – Hetrin, Rua 03, nº 200, Jardim Primavera, Trindade/GO, CEP: 75390-334.

F) PREÇO MENSAL DO CONTRATO: R\$ 4.200,00 (quatro mil e duzentos reais).

G) MULTAS APLICÁVEIS À LOCADORA: Atraso na entrega dos Equipamentos, ou no reparo ou substituição de Equipamentos defeituosos: 1% (um por cento) do preço mensal da locação do Equipamento, por dia de atraso.
H) COMUNICAÇÃO ENTRE AS PARTES: 1) Para a LOCATÁRIA: - Nome: Luciana Souza - E-mail: Luciana.souza@imed.org.br 2) Para a LOCADORA: - Nome: Charles Hytley - E-mail: charles@metrolabs.com.br - Telefone: (62) 3123-1595
I) Anexos: (a) Anexo I – Termo de Referência; (b) Anexo II – Proposta Comercial; e (c) Anexo III – Proposta Técnica.

Considerando que a referida contratação faz-se necessária para fins de dar suporte às atividades de gestão desenvolvidas pelo IMED junto ao Hospital Estadual de Trindade - HETRIN, tendo em conta que o **LOCATÁRIA** é a organização social responsável pelo gerenciamento, operacionalização e execução das ações e serviços de saúde da referida Unidade de Saúde, conforme Contrato de Gestão firmado com o Estado de Goiás, por intermédio de sua Secretaria de Estado de Saúde (Contrato de Gestão nº 037/2019 – SES / GO);

Pelo presente instrumento e na melhor forma de direito, as Partes qualificadas no **Item A do QUADRO RESUMO** tem entre si justo e acordado, o presente **CONTRATO DE LOCAÇÃO** (“Contrato”), em conformidade com as seguintes cláusulas e condições, bem como pela legislação vigente, e que mutuamente outorgam, aceitam e se obrigam a cumprir, por si e seus eventuais sucessores.

CLÁUSULA I – OBJETO

1.1 - O objeto do presente contrato será a locação pela **LOCADORA** à **LOCATÁRIA** dos Equipamentos listados e especificados no **Item B do QUADRO RESUMO** (“Equipamentos”), visando dar suporte às atividades de gestão desenvolvidas pelo **IMED** junto ao Hospital Estadual de Trindade - HETRIN.

1.2 – A LOCADORA declara neste ato que é legítima proprietária dos Equipamentos e que estes estão livres e desembaraçados de quaisquer ônus e de acordo com todas as normas vigentes, e serão entregues com todas as partes, peças e acessórios necessários para seu uso, adequados aos fins a que se destinam.

1.3. – Estão incluídas no escopo do Contrato, sem ônus adicional para a **LOCATÁRIA**, a montagem e instalação dos Equipamentos, quando necessário, bem como a manutenção corretiva dos Equipamentos e a assessoria técnica sobre os Equipamentos, sempre que solicitado pela **LOCATÁRIA**, e a manutenção preventiva a cada 06 (seis) meses, salvo se a legislação vigente, as normas técnicas aplicáveis ou as orientações do fabricante determinem manutenções em periodicidade inferior, quando tal periodicidade deve ser respeitada. Todos os serviços de manutenção serão objeto de relatórios específicos fornecidos pela **LOCADORA** à **LOCATÁRIA** na mesma data de realização da manutenção.

1.4. – A LOCADORA oferecerá, sempre que solicitado pela **LOCATÁRIA**, treinamento ao pessoal indicado pela **LOCATÁRIA**, para operar os Equipamentos.

1.5. - A LOCADORA declara, expressamente, ser legalmente habilitado para a execução do objeto deste Contrato e que possui capacidade técnica e operacional, além de mão-de-obra qualificada e experiência suficiente para atender às necessidades da **LOCATÁRIA**. A **LOCADORA** declara ainda neste ato, estar completamente apta e capaz tecnicamente para garantir a qualidade e eficácia dos Equipamentos, e que cumpre rigorosamente e integralmente todos os requisitos e exigências contidas nas normas, portarias, resoluções e regulamentações técnicas pertinentes, atuando em estrita observância às legislações vigentes.

1.6. – Integram o presente Contrato para todos os fins, os anexos previstos no **ITEM I do QUADRO RESUMO**.

1.6.1.- Em caso de conflito entre o disposto neste Contrato e seus anexos, prevalecerão os termos e condições deste Contrato. Em caso de divergência entre os anexos, eles prevalecerão na ordem em que estão listados.

CLÁUSULA II – DO LOCAL, DO PRAZO E DA FORMA DA ENTREGA E RETIRADA DOS EQUIPAMENTOS

2.1 – Os Equipamentos deverão ser entregues pela **LOCADORA** no local indicado no **ITEM E do QUADRO RESUMO**, montados e instalados, quando necessário, no prazo indicado no item **ITEM D do QUADRO RESUMO**.

2.2. – Caso a **LOCATÁRIA** não receba, em todo ou em parte, os Equipamentos dentro do prazo e no local acima estabelecidos em conformidade com as especificações e

quantidades indicadas neste Contrato, deverá comunicar a **LOCADORA**, por qualquer modo escrito, podendo aplicar à **LOCADORA** multa não compensatória prevista no **ITEM G do QUADRO RESUMO**, sendo o valor descontado de qualquer pagamento devido por força deste ou de outros contratos ou obrigações existentes entre as Partes ou cobrada judicial ou extrajudicialmente pela **LOCATÁRIA**.

2.2.1. – A penalidade estabelecida na Cláusula 2.2, acima, tem caráter não compensatório, não isentando a **LOCADORA** do cumprimento de quaisquer de suas obrigações previstas neste Contrato, especialmente a de entregar os Equipamentos em atraso, bem como da obrigação de indenizar integralmente a **LOCADORA** pelos danos decorrentes do atraso, e não prejudica o direito da **LOCADORA** de, a seu critério, dar por rescindido o presente Contrato.

2.3. - A **LOCADORA** deverá se responsabilizar pelo transporte dos Equipamentos sem qualquer custo ou despesa para a **LOCATÁRIA**, assegurando-se não só a integridade, como também as suas condições de esterilidade, conservação, manipulação e rastreabilidade.

2.4. - A entrega dos Equipamentos, somente será considerada cumprida quando do efetivo recebimento e aceitação do(s) mesmo(s) pela **LOCATÁRIA**. Porém, o recebimento e/ou a aceitação dos Equipamentos pela **LOCATÁRIA** não modifica, restringe ou elide a plena responsabilidade da **LOCADORA** quanto à sua entrega nas condições contidas neste Contrato e em seus anexos, nem invalida qualquer reclamação que a **LOCATÁRIA** venha a fazer em virtude de posterior constatação de unidade defeituosa ou fora de especificação, garantida a faculdade de troca/reparação, sem qualquer custo ou despesa para a **LOCATÁRIA**.

2.5. – Será de inteira responsabilidade da **LOCADORA** a entrega dos Equipamentos, acondicionados em perfeito estado de conservação e de utilização para os fins aos quais se destinam, nos exatos termos das suas especificações técnicas.

2.6. – A **LOCADORA** declara ter ciência de que a **LOCATÁRIA** exerce atividade essencial à saúde pública e que os Equipamentos são essenciais ao atendimento de tal finalidade e, portanto, a **LOCADORA** não poderá suspender a execução de suas obrigações contratuais sob qualquer hipótese.

2.7. – Não será admitida justificativa de atraso na entrega dos Equipamentos que tenha como fundamento o não cumprimento da sua entrega ou da entrega de suas partes e peças pelos fornecedores da **LOCADORA**.

2.8. – Após o encerramento do presente Contrato, a **LOCADORA** deverá retirar os Equipamentos no local especificado na Cláusula 2.1, arcando com todos os custos decorrentes, inclusive pela sua desmontagem e instalação, e os custos de transporte,

sempre em data e horário previamente acordados com a **LOCATÁRIA**, com antecedência mínima de 10 (dez) dias.

CLÁUSULA III – DO VALOR DA LOCAÇÃO

3.1. – O valor mensal total da locação é o previsto no **ITEM F do QUADRO RESUMO**.

3.1.1 - No valor da locação estão incluídos todos os custos, despesas, contingências e atividades necessárias à boa e fiel execução deste Contrato, incluindo, mas não se limitando ao transporte dos Equipamentos, seguros, todos os encargos sociais e previdenciários, tributos, contribuições parafiscais, despesas diretas e indiretas, benefícios, lucro e todos e quaisquer demais ônus que incidam sobre o escopo do Contrato.

3.2. - Os pagamentos serão realizados mensalmente e iniciados 30 (trinta) dias a contar da efetiva entrega dos Equipamentos no local e nas condições definidas na Cláusula II, condicionados ao aceite da **LOCATÁRIA** dos Equipamentos e à apresentação dos competentes documentos de cobrança e mediante transferência bancária em favor da **LOCADORA**, cujos dados encontra-se abaixo:

Dados Bancários: Sicoob/ AG.: 3300/ C.C.: 5788-6

3.2.1. – O recibo de locação deverá ser emitido no CNPJ da filial da **LOCATÁRIA** indicada no **ITEM A do QUADRO RESUMO**.

3.2.2. – O frete dos instrumentais, tanto para envio como para retorno, ficará a cargo da **LOCADORA**, devendo o mesmo ser especificado no Recibo de Locação.

3.3. - Todos os pagamentos estão condicionados à apresentação das certidões negativas de débitos válidas e sem pendências (exceto nos casos das certidões positivas com efeitos de negativas), quais sejam: federal conjunta, estadual, municipal, FGTS e trabalhista, e também, se e quando aplicável, do relatório das atividades desempenhadas no mês de apuração.

3.4. – O pagamento da locação está condicionado a que a **LOCADORA** tenha cumprido com todas as suas obrigações decorrentes do Contrato, incluindo as devidas manutenções, treinamentos e assessorias técnicas, e que os Equipamentos estejam plenamente funcionais e disponíveis para uso da **LOCATÁRIA**.

3.5. - A **LOCADORA** está ciente de que os pagamentos devidos por força deste Contrato estão condicionados ao repasse da verba necessária pela Secretaria de Estado de Saúde (SES/GO) à **LOCATÁRIA**. No caso de a Secretaria de Estado de Saúde (SES/GO) atrasar o repasse de um ou mais repasse(s)/custeio(s) mensal(is), o pagamento deverá ser disponibilizado à **LOCADORA** em até 10 (dez) dias úteis da regularização das pendências financeiras pelo Estado de Goiás, e a antes desse prazo a **LOCATÁRIA** não será considerada

inadimplente, não se aplicando o disposto na cláusula **3.6**, abaixo, restando vedado à **LOCADORA** emitir duplicatas e/ou realizar protestos e cobrar tais valores, tanto por meio extrajudicial, como judicial, suspender ou rescindir o Contrato.

3.6. - Atrasos de pagamento por culpa exclusiva e comprovada da **LOCATÁRIA** acarretarão a incidência de correção monetária pela variação do IPCA e juros moratórios de 0,5% (meio por cento) ao mês, que serão calculados proporcionalmente ao número de dias em atraso. Na hipótese de o IPCA do mês de pagamento ainda não ter sido divulgado, utilizar-se-á o do mês anterior. Qualquer encargo adicional ou disposição divergente constante do **Anexo I** ou qualquer outro anexo deste Contrato não será aplicável.

CLÁUSULA IV – DA VIGÊNCIA E DA RESCISÃO CONTRATUAL

4.1 - O Contrato terá pelo período indicado no **ITEM C do QUADRO RESUMO**.

4.2. - O presente Contrato poderá ser encerrado, nas seguintes hipóteses:

- a) por mútuo acordo, mediante assinatura de termo de encerramento correspondente;
- b) por conveniência, pela **LOCATÁRIA**, a qualquer momento, por aviso prévio, de qualquer forma escrita à **LOCADORA**, com antecedência de 30 (trinta) dias, sem que seja devido o pagamento de quaisquer multas e/ou indenizações de qualquer espécie;
- c) em razão de evento de força maior, devidamente comprovada, que impeça o cumprimento por quaisquer das Partes de suas obrigações contratuais e que perdure por mais de 60 (sessenta) dias.

4.3. - A **LOCATÁRIA** poderá rescindir o presente Contrato mediante simples comunicação escrita nos seguintes casos:

- a) Inadimplemento ou o cumprimento irregular de qualquer cláusula contratual, por parte da **LOCADORA**;
- b) Pedido de falência ou de recuperação judicial da **LOCADORA**;
- c) Imperícia, atraso, negligência, imprudência, dolo, má-fé ou desídia da **LOCADORA**, na execução do Contrato;
- e) Caso as multas aplicadas à **LOCADORA** superem 20% (vinte por cento) do valor total do Contrato; ou
- f) Por ordem da Secretaria de Estado de Saúde de Goiás.

4.4 - Em qualquer hipótese de encerramento do Contrato, deverá a **LOCATÁRIA** proceder a retirada dos Equipamentos nos termos da Cláusula 2.8.

4.5 - A **LOCADORA** tem pleno conhecimento de que foi contratada para prestar os Serviços objeto deste Contrato ao **LOCATÁRIO**, uma vez que este é o responsável pelo gerenciamento e execução das ações e serviços de saúde constantes no Contrato de Gestão firmado com o Estado de Goiás, por intermédio de sua Secretaria de Estado de Saúde (Contrato de Gestão nº 037/2019 – SES / GO), razão pela qual concorda, desde já, que caso o ente público intervenha, rescinda ou encerre, por qualquer modo ou razão, o referido contrato, o presente instrumento restará automaticamente rescindido, não fazendo a **LOCADORA** jus a qualquer tipo de indenização, qualquer que seja sua natureza, renunciando expressamente ao direito de pleitear quaisquer valores indenizatórios, em qualquer tempo ou jurisdição, junto ao **LOCATÁRIO**.

CLÁUSULA V – DA MANUTENÇÃO DOS EQUIPAMENTOS

5.1. - Os Equipamentos deverão ser entregues pela **LOCADORA** dentro dos padrões de qualidade, apresentação, e adequação às indicações de uso, de acordo com o estabelecido neste Contrato e com as normas sanitárias em vigor no país, novos, em perfeito estado, e livres de quaisquer defeitos, reservando-se ao **LOCATÁRIA** o direito de solicitar a troca imediata dos Equipamentos que apresentem incorreções ou problemas de qualidade, sejam diferentes das especificações requeridas pela **LOCATÁRIA** ou que se mostrem inadequados para os fins a que se destinam.

5.2. – A **LOCADORA** garantirá que os Equipamentos fornecidos nos termos do presente Contrato atendem a todos os requisitos legais e regulatórios exigidos a eles, incluindo, mas não se limitando, procedência, notas fiscais, romaneios e qualidade. Na hipótese de se constatar que os Equipamentos não atendem a quaisquer um dos requisitos ora mencionados, deverá proceder a substituição consoante disposto neste Contrato.

5.3. – Durante toda a vigência da locação, a **LOCADORA** reparará/e ou substituirá os Equipamentos, suas partes e/ou peças defeituosas, ou corrigirá problemas relacionados à sua instalação e montagem, sem qualquer ônus para o **LOCATÁRIA**, arcando inclusive com os custos de transporte, fretes, desinstalação e/ou reinstalação, quando necessário.

5.4. - Caso seja constatado defeito ou qualquer mau funcionamento nos Equipamentos, a **LOCADORA** deverá atender o chamado e, quando necessário, comparecer ao local em que os Equipamentos estiverem instalados no prazo de 24 (vinte e quatro) horas. O prazo para reparo e/ou substituição dos Equipamentos não poderá superar 2 (dois) dias úteis a contar da comunicação da **LOCATÁRIA**. Caso os Equipamentos não sejam reparados ou substituídos no prazo previsto nesta cláusula, aplicar-se-á à **LOCADORA** multa diária não compensatória prevista no **ITEM G do QUADRO RESUMO**, sendo o valor descontado de

qualquer pagamento devido por força deste ou de outros contratos ou obrigações existentes entre as Partes ou cobrada judicial ou extrajudicialmente pela **LOCATÁRIA**.

5.5. – Apenas caso a necessidade de reparo ou substituição decorra de comprovado mau uso dos Equipamentos pelo pessoal da **LOCATÁRIA**, a mesma arcará com os custos de reparo ou, caso o reparo seja comprovadamente impossível, de substituição. Neste caso, antes do reparo ou substituição, a **LOCADORA** deverá enviar à **LOCATÁRIA** um orçamento descrevendo os respectivos custos, que devem ser coerentes com as práticas de mercado. A responsabilidade total da **LOCATÁRIA** por danos aos Equipamentos não superará o custo do seu reparo ou, se este for comprovadamente impossível, o preço do Material danificado na data da assinatura do Contrato, descontado o desgaste natural. Em nenhuma hipótese a **LOCATÁRIA** será responsável por quaisquer outros danos, em especial por danos indiretos ou consequenciais, perda de receita, de contratos ou de oportunidades, danos morais e/ou lucros cessantes.

CLÁUSULA VI – CONFIDENCIALIDADE

6.1. - A **LOCADORA** se obriga a não revelar Informações Confidenciais a qualquer pessoa natural ou jurídica, sem o prévio consentimento por escrito da **LOCATÁRIA**. Entende-se por Informação(ões) Confidencial(is) toda e qualquer informação e dados revelados pela **LOCATÁRIA** à **LOCADORA** sejam eles desenvolvidos a qualquer momento pela **LOCATÁRIA**, sejam estes dados ou informações sejam eles de natureza técnica, comercial, jurídica, ou ainda, de natureza diversa, incluindo, sem limitação, segredos comerciais, know-how, e informações relacionadas com tecnologia, clientes, projetos, memórias de cálculo, desenhos, planos comerciais, atividades promocionais ou de comercialização, econômicas, financeiras e outras, que não sejam de conhecimento público, bem como todo e qualquer dado pessoal ou informação sensível de pacientes da **LOCATÁRIA**. A **LOCADORA**, por si e por seus subcontratados, empregados, diretores e representantes (todos, conjuntamente, “REPRESENTANTES”), obriga-se a não usar, nem permitir que seus REPRESENTANTES usem, revelem, divulguem, copiem, reproduzam, divulguem, publiquem ou circulem a Informação Confidencial, a menos que exclusivamente para a execução do Contrato.

6.2. - Caso se solicite ou exija que a **LOCADORA**, por interrogatório, intimação ou processo legal semelhante, revele qualquer das Informações Confidenciais, a **LOCADORA** concorda em imediatamente comunicar à **LOCATÁRIA** por escrito sobre cada uma das referidas solicitações/exigências, tanto quanto possível, para que a **LOCATÁRIA** possa obter medida cautelar, renunciar ao cumprimento por parte da **LOCADORA** das disposições desta Cláusula, ou ambos. Se, na falta de entrada de medida cautelar ou recebimento da renúncia, a **LOCADORA**, na opinião de seu advogado, seja legalmente compelida a revelar as Informações Confidenciais, a **LOCADORA** poderá divulgar as Informações Confidenciais às pessoas e ao limite exigido, sem as responsabilidades aqui estipuladas, e envidará os melhores esforços para que todas as Informações Confidenciais assim divulgadas recebam tratamento confidencial.

6.3. - A violação à obrigação de confidencialidade estabelecida nesta cláusula, quer pela **LOCADORA**, quer pelos seus REPRESENTANTES, sujeitará a **LOCADORA** a reparar integralmente as perdas e danos diretos causados à **LOCATÁRIA**.

6.4. - A **LOCADORA** se obriga a devolver imediatamente todo material tangível que contenha Informações Confidenciais, incluindo, sem limitação, todos os resumos, cópias de documentos e trechos de informações, disquetes ou outra forma de suporte físico que possa conter qualquer Informação Confidencial, tão logo ocorra término ou a rescisão do Contrato.

6.5. - A **LOCADORA** não fará qualquer comunicado, tirará ou divulgará quaisquer fotografias (exceto para as suas finalidades operacionais internas para a fabricação e montagem dos bens), ou revelará quaisquer informações relativas a este Contrato ou com respeito ao seu relacionamento comercial com a **LOCATÁRIA** ou qualquer Afiliada da **LOCATÁRIA**, a qualquer terceira parte, exceto como exigido pela Lei aplicável, sem o consentimento prévio por escrito da **LOCATÁRIA** ou de suas Afiliadas. A **LOCADORA** concorda que, sem consentimento prévio por escrito da **LOCATÁRIA** ou suas Afiliadas, como aplicável, não (a) utilizará em propagandas, comunicados ou de outra forma, o nome, nome comercial, o logotipo da marca comercial ou simulação destes, da **LOCATÁRIA** ou de suas Afiliadas ou o nome de qualquer executivo ou colaborador da **LOCATÁRIA** ou de suas Afiliadas ou (b) declarará, direta ou indiretamente, que qualquer produto ou serviço fornecido pela **LOCADORA** foi aprovado ou endossado pela **LOCATÁRIA** ou suas Afiliadas. Entende-se por afiliada qualquer empresa controlada por controladora de ou sob controle comum à **LOCATÁRIA**.

6.6. - A **LOCADORA**, por si e por seus colaboradores, obriga-se a atuar no presente Contrato em conformidade com a Legislação vigente sobre Proteção de Dados Pessoais e as determinações de órgãos reguladores/fiscalizadores sobre a matéria, em especial a Lei 13.709/2018, em especial com relação a todo e qualquer dado pessoal ou informação sensível de pacientes da **LOCATÁRIA**. A **LOCADORA** obriga-se a comunicar por escrito a **LOCATÁRIA** sobre qualquer infração à referida legislação, inclusive sobre o vazamento de dados.

6.7. – Esta obrigação subsistirá por tempo indeterminado, desde a assinatura do presente instrumento e após o seu encerramento por qualquer motivo.

CLÁUSULA VII – ANTICORRUPÇÃO E ÉTICA NOS NEGÓCIOS

7.1. - A **LOCADORA** declara estar em conformidade com todas as leis, normas, regulamentos e requisitos vigentes, relacionados com o presente Contrato. Assim, compromete-se a cumprir rigorosamente e de boa fé a legislação aplicável a este Contrato.

7.2. - Em virtude deste Contrato, nenhuma das Partes poderá oferecer, conceder ou comprometer-se a ceder a ninguém, ou receber ou concordar em aceitar de qualquer pessoa, qualquer pagamento, doação, compensação, benefícios ou vantagens financeiras

ou não financeiras de qualquer espécie que configurem uma prática ilegal ou corrupção, por conta própria ou de terceiros, direta ou indiretamente, devendo-se assegurar o cumprimento desta obrigação por parte de seus representantes e colaboradores.

7.3. - As Partes declaram e garantem categoricamente durante toda a vigência do presente Contrato, inclusive no que tange aos seus colaboradores e parceiros utilizados na execução do Contrato, a ausência de situações que constituam ou possam constituir um conflito de interesses em relação às atividades que devem ser realizadas de acordo com este documento legal. Da mesma forma, as Partes comprometem-se a adotar, durante toda a validade do Contrato, uma conduta apropriada para evitar o surgimento de qualquer situação que possa gerar um conflito de interesses. No caso de haver qualquer situação suscetível a levar a um conflito de interesses, as Partes comprometem-se a informar imediatamente por escrito a outra parte e a ater-se nas indicações que podem porventura ser assinaladas a esse respeito. O não cumprimento pelas Partes das obrigações assumidas sob esta cláusula, facultará a outra parte a possibilidade de rescindir o Contrato imediatamente, sem prejuízo das demais ações e direitos que possam ser exercidos de acordo com a lei.

7.4. - As Partes declaram e garantem que cumprem e cumprirão, durante todo o prazo de vigência do presente Contrato, todas as leis de anticorrupção, federais, estaduais e locais, decretos, códigos, regulamentações, regras, políticas e procedimentos de qualquer governo ou outra autoridade competente, em especial os preceitos decorrentes da Lei nº 12.846/13 (“Lei de Anticorrupção Brasileira”), abstendo-se de praticar qualquer ato de corrupção (“Atos de Corrupção”) e/ou qualquer ato que seja lesivo à administração pública, nacional ou estrangeira, que atente contra o patrimônio público nacional ou estrangeiro, contra princípios da administração pública ou contra os compromissos internacionais assumidos pelo Brasil.

7.5. – A **LOCADORA** declara que não contrata, direta ou indiretamente, mão de obra infantil (salvo na condição de aprendiz, a partir dos 14 anos), escrava, em condições análogas à escravidão, ou em condições sub-humanas, devendo garantir a seus empregados e contratados remuneração compatível com o piso salarial da categoria, jornadas e condições de trabalho conforme legislação em vigor.

7.6. - Na hipótese de qualquer das partes violar qualquer disposição prevista nesta cláusula e/ou qualquer obrigação legal prevista na legislação, operar-se-á a rescisão motivada, com aplicação das penalidades e indenizações por perdas e danos cabíveis.

7.7. – As Partes obrigam-se a agir de modo leal, responsável e probo, além de perseguir a boa-fé, para repelir quaisquer ações intencionalmente desleais, injustas, desonestas, prejudiciais, fraudulentas ou ilegais, sempre ancorados nas ações de transparência pública.

CLÁUSULA VIII – DISPOSIÇÕES GERAIS

8.1. - O presente instrumento e seus anexos, como também eventuais aditamentos, consubstanciam toda a relação contratual, ficando sem validade e eficácia quaisquer outros documentos aqui não mencionados e já assinados, correspondências já trocadas, bem como quaisquer compromissos e/ou acordos pretéritos, presentes e/ou futuros, os quais não obrigarão as Partes, sendo considerados inexistentes para os fins deste Contrato caso não seja observada a formalidade contida no item a seguir.

8.2. - Quaisquer alterações a este Contrato somente terão validade e eficácia se forem devidamente formalizadas através de aditamento contratual firmado pelos representantes legais ou procuradores das Partes.

8.3. - Se qualquer uma das disposições do presente Contrato for ou vier a tornar-se nula ou revelar-se omissa, inválida ou ineficaz não afetará ou prejudicará as cláusulas remanescentes, que continuarão com vigência, validade e eficácia plenas. Na ocorrência desta hipótese, as Partes farão todos os esforços possíveis para substituir a cláusula tida como nula, omissa, inválida ou ineficaz por outra, sem vícios, a fim de que produza os mesmos efeitos jurídicos, econômicos e financeiros que a cláusula original produziria, ou, caso isso não seja possível, para que produza os efeitos mais próximos possíveis daqueles inicialmente vislumbrados.

8.4. - O não exercício dos direitos previstos no presente Contrato, em especial no tocante à rescisão contratual e obtenção da reparação de danos eventualmente causados, bem como a tolerância, de uma parte com a outra, quanto ao descumprimento de qualquer uma das obrigações assumidas neste instrumento ou em seus anexos, serão considerados atos de mera liberalidade, não resultando em modificação, novação ou renúncia das disposições contratuais ora estabelecidas, podendo as Partes exercerem, a qualquer tempo, seus direitos.

8.5. - Em hipótese alguma o silêncio das Partes será interpretado como consentimento tácito.

8.6. - Declaram as Partes que toda e qualquer notificação, se necessário, poderá ser enviada e recebida eletronicamente aos contatos indicados no **ITEM H do QUADRO RESUMO**.

8.7. - O presente instrumento e seus anexos obrigam não só as Partes, como também seus eventuais sucessores a qualquer título.

8.8. - As Partes não poderão ceder, transferir ou, de qualquer modo, alienar direitos e obrigações decorrentes do presente Contrato, sem um acordo prévio e expresso uma da outra.

8.9. - O presente instrumento não estabelece entre as Partes nenhuma forma de sociedade, agência, associação, consórcio, ou responsabilidade solidária.

8.10. - Para a execução do objeto do presente Contrato, a **LOCADORA** declara que se acha devidamente habilitada e registrada nos órgãos competentes quando legalmente requerido.

Thiago Garcez Gonzales

8.11. – Sem prejuízo do pagamento de quaisquer penalidades estabelecidas neste Contrato, a **LOCADORA** deverá indenizar a **LOCATÁRIA** e/ou terceiros por todo e qualquer dano ou prejuízo que possa advir, direta ou indiretamente, do exercício de suas atividades ou serem causados por seus prepostos à **LOCATÁRIA** ou terceiros, do cumprimento ou do incumprimento das condições contratuais ou disposições legais ou regulatórias, ou problemas relacionados aos Equipamentos fornecidos.

CLÁUSULA IX – FORO

9.1. - Fica eleito, com expressa renúncia de qualquer outro, por mais privilegiado que o seja, o foro de São Paulo, Estado de São Paulo, para dirimir quaisquer controvérsias resultantes da interpretação e/ou execução do presente Contrato.

E, por estarem justas e contratadas, firmam as Partes e 02 (duas) testemunhas o presente Contrato para que produza os efeitos jurídicos desejados, reconhecendo a forma de contratação por meios eletrônicos, digitais e informáticos como válida e plenamente eficaz, ainda que seja estabelecida com a assinatura eletrônica ou certificação fora dos padrões ICP-BRASIL, conforme disposto pelo Art. 10 da Medida Provisória nº 2.200/2001 em vigor no Brasil. Sendo certo que na (i) na hipótese de assinatura eletrônica deste Contrato, ele produzirá efeitos a partir da abaixo mencionada, independentemente da data em que for assinado pelas Partes; e (ii) na hipótese de assinatura na forma física, o Contrato deverá ser entregue em 02 (duas) vias em igual teor e valor.

Trindade, 3 de setembro de 2026.

METROLAB SOLUCOES
EM ENGENHARIA
CLINICA
LTDA:32487278000121

Assinado de forma digital por
METROLAB SOLUCOES EM
ENGENHARIA CLINICA
LTDA:32487278000121
Dados: 2026.09.09 17:42:10
-03'00'

LOCADORA: METROLAB SOLUÇÕES EM ENGENHARIA CLÍNICA LTDA

ANDRE FONSECA
LEME:275226198
58

Assinado de forma
digital por ANDRE
FONSECA
LEME:27522619858

LOCATÁRIA: IMED – INSTITUTO DE MEDICINA, ESTUDOS E DESENVOLVIMENTO

Testemunhas:

1) 
Nome: Thiago Garcez Gonzales
C.P.F: 005.199.701-01

2) _____
Nome:
C.P.F.:

Documento assinado digitalmente
 LEONARDO COLOMBO
Data: 10/09/2026 19:40:00-0300
Verifique em <https://validar.iti.gov.br>

ANEXO I – TERMO DE REFERÊNCIA

A N E X O I

TERMO DE REFERÊNCIA

1. OBJETO:

LOCAÇÃO DE LAVADORA ULTRASSÔNICA, para fins de suporte às atividades de gestão desenvolvidas pelo IMED junto ao Hospital Estadual de Trindade - Walda Ferreira dos Santos (HETRIN).

2. DESCRIÇÃO DETALHADA:

LAVADORA ULTRASSÔNICA

Quantidade: 01

Capacidade interna: Mínimo de 40 litros.

Definição, Aplicação e Especificação mínima do equipamento:

- Equipamento utilizado para auxiliar na limpeza de peças ou partes, retirando toda sujeira e impureza encontrada na superfície e nas reentrâncias minúsculas e mais profundas através de ultrassom, que consiste na transformação de energia elétrica em energia mecânica. Não é passível de aprovação no item lavadora ultrassônica a tecnologia híbrida (jatos de ultrassom e termodesinfecção).
- Características mínimas:
- **ESTRUTURA DE CONSTRUÇÃO:**

- Equipamento microprocessado para lavagem de materiais canulados e instrumentais através de energia ultrassônica com frequência aproximada de 40Khz.
- Gabinete construído em aço inox AISI-304 escovado.
- Possui sistema de alarme, programação e memória, com painel e display.
- Material de confecção totalmente em aço inoxidável, tampa superior, sistema de aquecimento de solução e sistema de enxague.
- Sistema com adaptadores específicos para cada diâmetro de canulados, proporcionando maior eficiência de limpeza.
- Comando isolado do sistema de geração de ultrassom que evita a interferência na comunicação.
- Cuba com cantos arredondados e acabamento polido, minimizando o acúmulo de resíduo e maximizando a limpeza.
- Dotado de sistema automático de dosagem de detergente e drenagem automática.
- Mínimo 10 ciclos automáticos, sendo os quatro primeiros previamente determinados.
- Possuir controlador lógico programável com tela Touch Screen colorida de simples operação que permite ao operador a configuração de cada uma das fases do ciclo.
- Tampa tipo basculante, que permite uma vedação plena através de guarnição de silicone e dotada de sistema de segurança, que impede o funcionamento do equipamento caso a tampa esteja aberta.
- Pés niveladores.

- Dotado de sistema de controle de níveis, onde o nível baixo protege a resistência e os transdutores.
- Termostato de segurança da resistência com rearme manual que impede o acionamento da resistência no caso de uma sobre temperatura.
- Botão de emergência no painel frontal para eventuais falhas em outro dispositivo de segurança.
- Sensor indutivo de fechamento da tampa que impede o início do ciclo com a tampa aberta, evitando possíveis queimaduras ou contato com a solução de limpeza.
- Cesto interno dotado de no mínimo dez bicos adaptadores com engates rápidos. Copo adaptador para cada tipo de canulado, podendo o diâmetro do engate da tampa variar entre 1 e 10 mm.
- Sistema de drenagem automática.
- Princípio de funcionamento por enxague e limpeza.
- Dimensões estimadas:
- Dimensões Externas (LxCxA cm):
- Dimensões (LxPxA): 30 x 70 x 20 cm
- Alimentação: 220V, frequência 60 Hz;

ACESSÓRIOS:

- Osmose reversa:

- Por osmose reversa com características mínimas a apresentar: Produção compatível com o consumo do equipamento; Montagem na parede ou base; Manômetro para leitura de pressão na linha de abastecimento, registro esfera.
- Reservatório com sistema de controle de nível; Pré-filtro para sedimentos; Filtro de carvão ativado; Pós filtro; Membrana de osmose reversa; Sistema automático de funcionamento; Sistema automático de proteção contra falta de água;
- Deve acompanhar todos os materiais, cabos, componentes e acessórios necessários à perfeita instalação e operação do equipamento configurado nessa especificação.
- IMPRESSORA: Térmica, acoplada e relatório de impressão que conste valores de: Tempo de operação; Ciclos; Fases de ciclos; Temperaturas; Pressões; Data e hora do ciclo; Falhas no processo; Interrupção do ciclo.
- 04 conectores tipo universal, 04 conectores tipo rosca.
- 02 cestos de aço inox.
- 01 cesto pequeno aço inox.
- 01 kit insumos reagentes;
- Demais acessórios: Fornecimento de todos os cabos elétricos, mangueiras e cavaletes pneumáticas e hidráulicas, conectores e acessórios indispensáveis ao funcionamento do equipamento considerando a sua funcionalidade e ligação aos suprimentos.
- Manual técnico e operacional do equipamento em português;

EXIGÊNCIAS TÉCNICAS OU NORMATIVAS:

- Apresentar documentos comprobatórios da existência de registro ativo na ANVISA, para o referido objeto e atendimento às normas técnicas vigentes e aplicáveis;
- Qualificação térmica de instalação, operação e desempenho de acordo com as normas aplicáveis. Demais testes de comprovação técnica de funcionamento. E insumos necessários para a realização dos testes.
- Assistência técnica durante todo o período de locação;
- Treinamento operacional para usuários e equipe de Engenharia Clínica, sem ônus adicional;

SERVIÇOS DE SUPORTE E MANUTENÇÃO

- Execução de manutenções preventivas conforme recomendações do fabricante;
- Manutenção corretiva quando necessário, com substituição imediata de equipamento em caso de falha;
- Disponibilização de equipamento reserva em caso de retirada para manutenção corretiva, garantindo a continuidade do serviço.

Service Level Agreement – SLA (Contrato de Nível de Serviço)

Para garantir a qualidade na prestação do serviço, a empresa contratada deverá cumprir os seguintes SLAs (Service Level Agreements) para atendimento técnico:

Caso seja constatado defeito ou qualquer mau funcionamento no Equipamento, a LOCADORA deverá atender o chamado e, quando necessário, comparecer ao local em que o Equipamento estiver instalado no prazo de até 24 (vinte e quatro) horas. O prazo para reparo e/ou substituição do Equipamento não poderá superar 2 (dois) dias úteis a contar da comunicação da LOCATÁRIA. Caso o Equipamento não sejam reparados ou substituídos no prazo previsto nesta cláusula, aplicar-se-á

à LOCADORA multa diária não compensatória prevista abaixo, sendo o valor descontado de qualquer pagamento devido por força deste ou de outros contratos ou obrigações existentes entre as Partes ou cobrada judicial ou extrajudicialmente pela LOCATÁRIA.

O não cumprimento dos prazos estabelecidos resultará em:

- **Advertência formal** na primeira ocorrência;
- **Multa de 3% sobre o valor mensal do contrato** para cada reincidência;
- **Rescisão contratual**, caso o descumprimento dos SLAs comprometa a continuidade dos serviços.

3. PRAZO ESTIMADO DE ENTREGA: Até 07 dias contados da assinatura do contrato.

4. PRAZO DE VIGÊNCIA DO CONTRATO:

Até a completa execução, pela CONTRATADA de todas as suas obrigações contratuais, respeitado o limite da vigência do Contrato de Gestão (24/08/2027).

5. EXPERIÊNCIA ANTERIOR: Deverá a proponente comprovar experiência na execução do objeto da RFP e deste Termo de Referência, sendo certo que tais documentos deverão ser apresentados juntamente com os documentos de habilitação, sob pena de desclassificação.

6. CRITÉRIO DE JULGAMENTO DAS PROPOSTAS: Menor preço mensal.

7. DO PAGAMENTO

Os pagamentos serão realizados mensalmente e iniciados 30 (trinta) dias a contar da efetiva entrega dos Equipamentos no local e nas condições definidas,

condicionados ao aceite da LOCATÁRIA dos Equipamentos e à apresentação dos competentes documentos de cobrança e desde que o IMED tenha recebido o repasse do Estado de Goiás o valor do custeio/repasso correspondente ao mês de locação, do que o proponente, desde já, fica ciente e concorda.

ANEXO II – PROPOSTA COMERCIAL



PROPOSTA COMERCIAL 26/0083

AO
IMED - Instituto de Medicina, Estudos e Desenvolvimento

Prezados Senhores,

Vimos pela presente, apresentar nossa Proposta Comercial para atender à Requisição RFP 11/2026 LOCAÇÃO DE LAVADORA ULTRASSÔNICA, voltado para dar suporte às atividades de gestão pelo IMED junto ao Hospital Estadual de Trindade - Walda Ferreira dos Santos (HETRIN).

Razão Social:	METROLAB SOLUÇÕES EM ENGENHARIA CLÍNICA LTDA
CNPJ/CPF:	32.487.278/0001-21
Inscrição Estadual:	10.781.375-0
Endereço:	RUA C155, Nº 789, QD 365, GOIÂNIA-GO
Telefone:	62 3123-1595
E-mail:	charles@metrolabs.com.br
Contato:	Charles Hytley
Dados Bancários:	756 SIC00B, AG 3300 CC 5788-6

B – PROPOSTA DE PREÇOS

Descrição	Quantidade	Valor mensal
Lavadora Ultrassônica	1 und	R\$ 4.200,00 (quatro mil duzentos reais)

A validade da proposta é de 120 (cento e vinte) dias a contar de sua apresentação.

O preço ofertado inclui todos os custos e despesas diretos ou indiretos inerentes à completa execução do objeto, incluindo custos de pessoal, encargos trabalhistas, previdenciários, securitários, impostos e tributos de qualquer natureza.

Declaramos aceitar e cumprir com todos os requisitos da RFP, e que os preços propostos contemplam todas as atividades e obrigações previstas no Anexo I – Termo de Referência da RFP, sendo que nenhum valor adicional será cobrado do IMED pelas mesmas.

Goiânia, 20 de agosto de 2026.


CHARLES HYTLEY SANTOS TEIXEIRA
CPF: 030.452.081-00
SÓCIO ADM

32.487.278/0001-21
METROLAB SOLUÇÕES EM
ENGENHARIA CLÍNICA LTDA
Rua C-155, Nº 789 Qd. 365 Lt. 8
Jardim América CEP: 74275-150
GOIÂNIA - GO

ANEXO III – PROPOSTA TÉCNICA



Metrolab's
Soluções em Engenharia Clínica



www.metrolabs.com.br



+55 62 3123-1595

Metrolab Solucoes em Engenharia Clinica Ltda CNPJ: 32.487.278/0001-21 IM: 4743504 IE: 10.781.375-0

Fone: (62) 3123-1595 / (62) 9 9907-0106 E-mail: comercial@metrolabs.com.br charles@metrolabs.com.br

Cliente: Imed – Instituto De Medicina, Estudos E Desenvolvimento

Unidade: Trindade

Contato: João Marcos

20/08/2026 Proposta Válida para 180 dias

Orçamento nº 26/0083

PROPOSTA TÉCNICALOCAÇÃO DE LAVADORA ULTRASSÔNICA

LAVADORA ULTRASSÔNICA MEDISAFE MED11131



Registro Anvisa 10259750040

Metrolabs Soluções em Engenharia Clínica Inspeções e Ensaios Científicos

Medisafe



SI PCF

User Manual



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1. Introduction

User Manual



1-1 Medisafe Contact Details**United Kingdom**

(Manufacturing, Sales, Customer Service & Technical Support)

Medisafe UK Ltd
Unit 1 Twyford Industrial Estate
Twyford Road
Bishop's Stortford
Hertfordshire CM23 3LJ
England

Tel: +44 (0) 1279 461641

Fax: +44 (0) 1279 461643

E-mail info@medisafeinternational.com

www.medisafeinternational.com

Introduction

**Important**

Read this entire manual before attempting to install, operate or perform any maintenance on the Sonic Irrigator Parametric Controlled Flow (SI PCF) Ultrasonic Cleaning System. Ensure all appropriate personnel understand the contents of this manual.

This Operating Manual contains important information on proper use and maintenance of the SI PCF Ultrasonic Cleaning System. All personnel involved in the use and maintenance of this equipment must carefully review and comply with the warnings, cautions and instructions contained in this manual. These instructions are important to protect the health and safety of personnel operating the Ultrasonic Cleaning System and should be retained in a conveniently accessible area for quick reference.

Advisory

A listing of the *Safety Precautions* to be observed when operating the SI PCF Ultrasonic Cleaning System is found in Section 1-5 of this manual. Do not operate the equipment until you have become familiar with this information.

1-2 Independent Monitoring

Important Note for the Product Owner

It is advised that an independent monitoring system is fitted in accordance with ISO 15883-1:2009 - Washer-disinfectors.

1-3 Memorandum of Registration

Important

The person undertaking the installation must complete this Memorandum of Registration. In the event of a Warranty Claim, the information contained within this Registration is your evidence that the product has been correctly installed.

Important Note for the Installer

This *Memorandum of Registration* MUST be completed by the person undertaking installation and witnessed by the owner of the product. For installation instructions and contact information for qualified personnel who can perform the installation, please contact Medisafe (see section 1-1).

Failure to provide this evidence in the event of a warranty claim may result in the claim being rejected (*this does not affect your statutory rights as a customer*).

Owner Name:	
Installation Address:	
Installation Date:	
Model No.:	
Serial No.:	
Software Version:	
Installed by:	
Witnessed by:	

Service and Maintenance Requirements

The SI PCF should be serviced on a regular basis to ensure that the product continues to perform in accordance with its design parameter, see section 6-7 for more information.

1-4 SI PCF Warranty Registration

Important Note for the Installer

This *Registration Form* MUST be completed by the person undertaking installation and witnessed by the owner of the product. In the event of a Warranty Claim, the information contained within this Registration is your evidence that the product has been correctly installed. Failure to provide this evidence in the event of a warranty claim may result in the claim being rejected (*this does not affect your statutory rights as a customer*). A copy of this form must be sent to your local Medisafe authorised distributor to validate the warranty.

Tests parts one and two must be completed by the engineer commissioning the SI PCF for warranty registration purposes. Where no value is required write pass or fail with a comment if necessary.

For installation instructions and contact information for qualified personnel who can perform the installation, please contact Medisafe (see section 1-1).

Owner Name:	
Installation Address:	
Installation Date:	
Model No:	
Serial No:	
Software Version:	
Installed by:	
Witnessed by:	
Position:	

Part 1, Test Type	Acceptable Value	Result	Comments
Drains remove effluent effectively	-		
Phase sequence, Pump Rotation	-		
Support bases secure	-		
There is no evidence of interference to or from other equipment connected to the same services	-		
Hot Water Hardness (As specified by WD Manufacturer)	125 ppm (max)		
Cold Water Hardness (As specified by WD Manufacturer)	125 ppm (max)		

Part 1, Test Type	Acceptable Value	Result	Comments
Hot Water Temperature	50°C (122°F) min 80°C (176°F) max		
Cold Water Temperature	5°C (41°F) min 30°C (86°F) max		
Hot Water Pressure	2 - 5 bar (30 - 70 psi)		
Cold Water Pressure	2 - 5 bar (30 - 70 psi)		
Part 2, Final rinse water	Acceptable Value	Result	Comments
Rinse water supply Type	RO, DI, Softened		
If softened, Hardness	< 125 ppm		
Water Pressure	2 - 5 bar (30 - 70 psi)		
Temperature	5°C (41°F) min 80°C (176°F) max		
Electrical conductivity	<30µS/cm (RO) <10µS/cm (DI) <300µS/cm (Soft)		

Signed	Name	Date

Comments / remedial work	
-----------------------------	--

1-5 Safety Precautions

The following *Safety Precautions* **must** be observed when operating or servicing the SI PCF. WARNING indicates the potential for personal injury and CAUTION indicates the potential for damage to equipment. For emphasis, certain *Safety Precautions* are repeated throughout the manual. **It is important to review ALL Safety Precautions before operating or servicing the unit.**

Warning – Breathing Hazard	
	Some cleaning solutions emit harmful vapours. Only use cleaning solutions in well-ventilated areas. Do not inhale vapours. Do not permit solution vapours to exceed maximum allowable concentrations in the work area. Ensure adequate ventilation.
Warning – Chemical Burn and/or Eye Injury Hazard	
	• Detergents are caustic and can cause adverse effects to exposed tissues. Do not get in eyes, on skin or attempt to ingest by mouth. • Read and follow precautions and instructions on detergent label and in the Material Safety Data Sheet (MSDS) prior to handling chemical, refilling chemical containers or servicing chemical injection pumps and lines. • Wear appropriate Personal Protective Equipment (PPE) whenever handling chemicals or servicing chemical injection pumps and lines. This should include plastic gloves, goggles or full-face visor, and disposable plastic apron. • Wear appropriate Personal Protective Equipment (PPE) whenever removing baskets or parts from cleaning chamber. • In case of body contact with chemical, always follow emergency procedure given in that chemical's MSDS or call emergency services. • Use a funnel when transferring any chemical from one container to another.
Warning – Burn Hazard	
	• Since temperatures within the unit can reach 92°C (198°F) during and after operation, take care when opening lid at the end of a cycle. Allow sufficient time for items to cool before handling, cleaning or maintenance procedures. • Wear appropriate Personal Protective Equipment (PPE) whenever reaching into Chamber after a thermal disinfection operation. • Under no circumstances attempt to forcibly open the lid during operation. • During reloading of instruments in the re-wash program the water temperature within the unit can reach 60°C (140°F), take care when opening lid and reloading the instruments.

Warning – Explosion Hazard	
 Warning	Use only water or water-detergent mix in cleaning chamber. Never use flammable or combustible cleaning liquids. Fire or explosion could result.
Warning – Electric Shock Hazard	
 Warning	• To prevent the risk of fire or electric shock, do not expose equipment to unnecessary moisture. Always ensure that all external surfaces are dried after each cycle. • When removing a basket, allow to drain into the chamber before moving to the next cleaning station. Excess water spillage may cause electrical shock and serious injury. • Since dangerous high voltages are present inside the unit, keep the left cabinet door closed and locked at all times. • Disconnect all utilities to unit before servicing. Do not service unit unless all utilities have been properly locked out. Always follow local occupational health and safety regulations, as well as electric and plumbing codes. • Isolate electrical supply by turning the buildings disconnect switch to OFF before checking or replacing any parts. Electrical shock can cause serious injury.
Warning – Slipping Hazard	
 Warning	To avoid slippery floor conditions, immediately wipe up any spilled liquid or condensation. If spills or leaks could contain detergents or other chemicals, follow safety precautions and handling procedures set forth on detergent or chemical label and/or MSDS.
Warning – Personal Injury and/or Equipment Damage Hazard	
 Warning	• Only Medisafe or Medisafe-trained service personnel must make repairs and adjustments to this equipment. Maintenance performed by unqualified personnel or installation of unauthorized parts could cause personal injury, result in improper equipment performance, invalidate the warranty, or result in costly damage. Contact Medisafe regarding service options. • Regularly scheduled preventive maintenance, in addition to the faithful performance of routine maintenance described within the service manual, is required for safe and reliable operation of this equipment. Contact Medisafe to schedule preventive maintenance. • Failure to perform periodic service inspections of the machine could result in serious personal injury or equipment damage. • Do not wear loose fitting clothing, neckties or jewellery that could become entangled in moving parts. • Never reach into a chamber when unit is in operation. • Always use a basket to reprocess instruments within the unit.

Caution – Possible Equipment Damage**Caution**

- Never place items or person(s) on the lid.
- Do not drop items into the wash tank as this could damage the ultrasonic transducers.
- Do not place items directly into the wash tank or allow them to make contact with the tank sides.
- Never scratch chamber walls. This can increase cavitation erosion.
- Do not load basket with instruments pointing at the lid.
- Do not overload the basket, maximum load of 10kg (22lbs).
- Do not allow Luer pipes to protrude from the basket.
- When choosing a detergent, select one with a low chloride content. Detergents with a high chloride content can be harmful to stainless steel.
- Repeated fuse blows or circuit breaker trips indicate a short circuit or overload. Have a fully trained technician locate and correct situation.
- Use nonabrasive cleaners when cleaning unit. Follow directions on container and rub in a back-and forth motion, in same direction as surface grain. Abrasive cleaners damage stainless steel. Cleaner rubbed in a circular motion or applied with a wire brush or steel wool will scratch and dull stainless steel.
- Avoid running equipment into the Control Panel or Touch Screen to prevent damage to controls.

Caution – Chemical**Caution**

- Chemical bottles must be connected to the correct port. Otherwise, wash efficiency and/or rinsing will be compromised.
- Check chemical bottles are in date before use

Caution – Instrument Care**Caution**

- Always confirm compatibility with the instrument manufacturer.
- Always follow the manufacturer's instructions if processing instruments with special characteristics e.g. fibre optics or rigid optics.
- Whether pre or post processing instruments, always follow the manufacturer's instructions.
- Always attach tubing to a suitable size distal connector for instruments being cleaned or to a quick connect port if the instrument has one.
- Always open box jointed instruments.
- Always ensure taps are open on cannulated instruments.
- Always disassemble instruments that are designed to be taken apart.
- Always attach at least one Luer pipe to each basket manifold if cannulated instruments are not being cleaned, this will aid water circulation.
- Visually inspect instruments after reprocessing
- If any instruments became detached from the Medisafe connection tubing during processing, they should be reprocessed after ensuring that the Luer connection is firmly seated.
- Do not connect more than ten instruments to the Si Robotic Basket as this will reduce the water pressure and compromise effective cleaning.
- Do not connect more than six instruments to the Xi Robotic Basket as this will reduce the water pressure and compromise effective cleaning.

1-6 Training Personnel

The owner of this equipment has the responsibility for training the users and keeping the appropriate records.



Warning

There should be regular training of all personnel concerned with the operation and maintenance of the equipment. The training schedule shall include:

- Operation of the machine (see section 2-10, 3-1, 3-4-1, 3-4-2, 3-5, 3-7, 3-8, 3-9, 3-10 and 3-11).
- Safe use of machine (see section 1-5)
- Chemical handling (see section 3-6)
- Emergency Procedures e.g. how to handle the load in case of aborted cycle (see section 3-12 and 3-13)
- Regular maintenance procedures (see section 3-15 and 3-16)
- Troubleshooting (see section 4)

The following table can be used for keeping training records.

Date	Name	Title of Training	Signature of Trainer

1-7 Compliance

The SI PCF has been designed to perform within the guidelines recommended by international decontamination Standards. A stringent quality control program ensures that every unit is manufactured and tested under controlled conditions to ensure that all products perform identically.

Commitment to RoHS and WEEE Requirements

Medisafe is committed to meeting or exceeding the requirements of the RoHS CE Marking directive (2011/65/EC) (*Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment*).

Medisafe is also committed to meeting all requirements of the WEEE directive (2012/16/EU) (*Waste Electrical and Electronic Equipment*).

WEEE and Battery Disposal



Waste electrical and electronic products must not be placed in the general refuse but collected separately. Separately collected WEEE products are to be sent to an approved recycling or disposal operators for safe recycling, recovery or reuse.

Medisafe UK Ltd is registered with the "B2B Compliance" Scheme. B2B Compliance on behalf of Medisafe, takes on the legal responsibilities of the reporting, collection and treatment of, all WEEE that Medisafe UK Ltd is obligated for - and ensures that the appropriate recycling targets are met. For independent confirmation of Medisafe UK Ltd status can call B2B Compliance on 0845 680 9829 or visit www.b2bcompliance.org.uk.

To fulfil our B2B WEEE take-back obligations, B2B Compliance will undertake the appropriate collection and disposal of obligated products of Medisafe UK Ltd.

If a Medisafe Product has reached its end of life, please contact B2B Compliance collections team on 0845 680 9829 or collections@b2bcompliance.org.uk to arrange collection and treatment.

Otherwise, please recycle where facilities exist. Check with your Local Authority or Distributor for recycling advice.

Declaration of CE Conformity

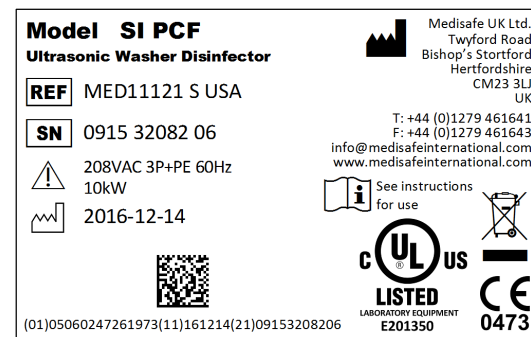
The SI PCF is designed and manufactured in the UK by Medisafe UK Ltd. and complies with the essential requirements of the Medical Devices Directive 93/42/EEC (where appropriate). All products are CE compliant and are registered as Class IIb devices through the application of rule 15 within Annex IX of the Medical Devices Directive 93/42/EEC.



1-8 Product Identity

The model and serial number label are located on the inside panel of the chemical compartment.

Example of serial number label:



The software version is shown on the front panel display when the unit is first switched on.

1-9 Manufacturer Information

Medisafe UK Ltd
Unit 1 Twyford Industrial Estate
Twyford Road
Bishop's Stortford
Hertfordshire CM23 3LJ
England

Tel.: +44 (0) 1279 461641
Fax: +44 (0) 1279 461643

E-mail info@medisafeinternational.com

1-10 Intended Use

The Medisafe Sonic Irrigator PCF is a High-Pressure, Ultrasonic, Flushing Washer Disinfector for the medical market. It is intended to provide cleaning and low-level thermal disinfection of surgical instruments, including complex lumen/cannulated devices, such as robotic surgical instruments.

This is achieved through a combination of ultrasonics and a flushing action to remove debris from both the outside and inside (hollow instruments only) of items placed within the wash tank.

Note: *The SI PCF Washer has been validated for the cleaning and low-level thermal disinfection of surgical instruments and devices, including complex lumen/cannulated surgical instruments and devices such as robotic surgical instruments. Testing to validate cleaning and disinfection efficacy for a specific instrument is the responsibility of the instrument manufacturer. Consult the instrument manufacturer's instructions regarding cleaning and disinfection.*

Note: *If the equipment is used in a manner not specified by the manufacturer, the effectiveness and protection provided by the equipment may be impaired.*

1-11 Performance

Washing is achieved using a unique, specially formulated and clinically validated decontamination fluid (EDA+ or 3E-Zyme®), which is introduced into the machine during the cycle.

This machine has a class AB weir incorporated into the tank design to comply with most water authority regulations.

A stringent quality control program ensures that every unit is manufactured and tested under controlled conditions to ensure that all units perform identically.

1-12 Cycle Record

During the cycle, parameters are reported at key stages of the process as an ASCII serial data stream via the RS232 port. This can then be logged either on a printer (see section 2-6-2 and 2-10) or on a PC (see section 2-11).

The on-board cycle log can be download via a USB flash drive (see section 3-14).

1-13 Cycle Failure

The SI PCF is designed to perform within strict and carefully controlled tolerances. If an unexpected condition occurs during a wash cycle, the system will abort the cycle and report an error, see section 3-12 for more details.

1-14 Concept Summary

The SI PCF has the ability to wash up to twenty instruments.

There are six pre-defined user selectable programs with *Pre-wash*, *Wash*, *Rinse* and *Disinfection* stages tailored to clean a multitude of different loads.

The program parameters can also be changed within specified limits by an engineer during installation or service.

The SI PCF has an interlock system that prevents a cycle being started with the lid up.

Load Instruments

The user loads the instruments into the basket, places it into the machine and presses the touch screen to lock the lid.

Prewash

The cycle begins with a cold-water fill to the mid-level; the spray and irrigation valves are opened alternately with the pump running for the specified time. The water is then drained.

Wash

At the main wash stage, the tank is filled to the top level with a cold and hot water mix to attain a set temperature. Detergent is also added at this point. The pump is pulsed on and off, to even out the temperature, fill all cavities, and to mix the chemical thoroughly. Once the tank is full the ultrasonics degas the tank by pulsing on and off to remove any dissolved air. A period of irrigation follows in order to flush any material from inside the instruments. The ultrasonics then alternate with irrigation for the set period of time. The water is then drained.

Rinse

The tank is filled to the mid-level; and heated to the set point. The machine then alternates between the spray and irrigation for the pre-defined time. The water is then drained.

For some programs this stage is repeated.

Disinfection

If disinfection is required, the machine is then filled to the minimum level with hot water and heated up to the pre-set temperature (91°C / 196°F) for 3 minutes. The water is then drained.

Cooling

To disperse the vapour in the chamber, the machine opens the drain valve and fills with cold water for several minutes.

Unload

The user touches the screen to acknowledge the end of the cycle, which unlocks the lid and allows the basket to be removed.

1-15 General Safety

This equipment is not suitable for use with flammable materials or gases, and should not be used for any purpose other than that defined by the manufacturer as a high pressure sonic irrigation washer disinfectant.

1-15-1 Chemicals

Since this equipment contains a high power heating device, the use of substances or chemicals, other than those specified by Medisafe, may be hazardous. Therefore, always read the manufacturer's chemical safety information before use and never use toxic, corrosive, or flammable liquids.

Using non-approved chemicals may cause damage to your machine and could void your warranty and guarantee of performance.

1-15-2 Decontamination

In the event that this product needs to be returned to the supplier, it **MUST** first be fully decontaminated before transporting. The *Decontamination Certificate* (see section 3-16-4) must also be completed and displayed in a prominent position when returned with the product.

1-15-3 Heat



Since temperatures within the unit can reach 92°C (198°F) during and after operation, take care when opening lid at the end of a cycle. Allow sufficient time for items to cool before handling.

1-16 Electrical Safety



Dangerously high voltages are present inside the machine. Do not remove any panelling, or attempt to gain access to the inside of the machine, keep the left cabinet door closed and locked at all times. Refer servicing and repair to qualified personnel only.

It is expected that any person servicing or repairing the SI PCF will be a competent engineer with an understanding of electrical safety, and knowledge of three phase power. It is also crucial to understand the risks of working with electrical appliances that use water. Caution must be taken at all times to ensure a safe environment.

To avoid risk of electric shock, this equipment must only be connected by a fully qualified electrician and to a mains supply with a protective earth.

To prevent the risk of fire or electric shock, do not expose equipment to unnecessary moisture. Always ensure that all external surfaces are dried after each cycle.

The key must only be available to a Responsible Body.

1-17 Service Contracts & Warranty

Your SI PCF is supplied with a conditional 12-month parts warranty, which is effective from the date of installation.

Medisafe (UK) offers a range of Service Contracts and Extended Warranty Packages to provide continuous maintenance and breakdown cover once the original warranty has expired.



Hazards can result from unauthorized modification of the machine. No modification of this equipment is allowed. Any modification to this equipment will void the warranty.

1-18 Validation Option

Medisafe (UK) can also provide a *Validation Service* to address the essential local regulation requirement. The work will be carried out by authorised Medisafe engineers to ensure your SI PCF continues to conform to local and national guidelines.

For more information on service or any of these options, please contact Medisafe or your regional distributor.

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2. Installation

User Manual



2-1 Transport and Storage

The permissible environmental conditions for transport and storage of a new or used SI PCF must adhere to the environmental conditions for altitude, temperature and relative humidity.

2-1-1 Marking

The markings on the packing crate stipulate the machine's storage conditions and handling information.



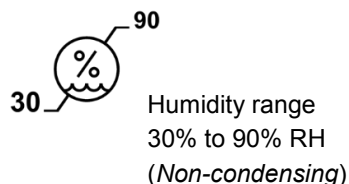
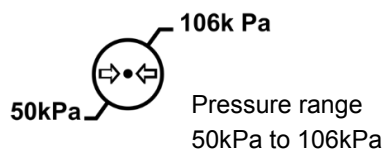
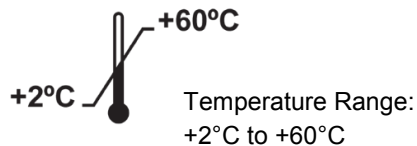
Keep dry



This way up'

2-1-2 Environmental

This equipment can be transported and stored safely, in the following environment:



2-2 Lifting

Lifting and manoeuvring the SI PCF in its packing crate must be done using a pallet truck or forklift truck able to take a load in excess of 250kg.

2-3 Unpacking

Retain all packaging materials, if for any reason the unit needs to be returned to the supplier, then the original crate and packaging materials should be re-used.

Carefully unpack your SI PCF by removing the top panel first. The front panel of the packing crate is designed to be used as a ramp to aid in getting the machine off the crate. Once off its base and unpacked, it can then be moved across a level floor on its castors.

This equipment is not intended to be routinely moved, wheels are provided only to facilitate installation and servicing by a service engineer.

2-4 Returns

Before transporting a used SI PCF, it is vital that all fluid is thoroughly drained from the machine. If returning the unit to your supplier or Medisafe UK Ltd it **MUST** first be fully decontaminated before transporting.

The *Decontamination Certificate* must also be completed and displayed in a prominent position when returned with the product (see section 3-16-4).

2-5 Enclosures Check List

The unit is supplied with a range of accessories to enable easy installation and efficient operation. Ensure that all these items are present before attempting to install or operate the unit. Complete the following Enclosures Check List and notify your supplier of any shortages or damaged components as soon as possible.

The SI PCF comes with one basket (standard), the type of basket and typical accessories supplied for each SI PCF variant are shown in the tables below. Replacement items can be ordered, see below list for details.

Note: The below depends on your machine type, please refer to what has been specified on your order.

2-5-1 Standard PCF S

Standard PCF S Machine Part Numbers						
MED11100	MED11110	MED11122	MED11121	MED11121UL	MED11120	MED11123

Quantity	Part No.	Description	Checklist ☒
1	MED8601	Standard Basket	
1	MED1014x	Thermal printer (For country specific version see 2-6-2)	
1	MP21424	Standard PCF Accessory Kit	

2-5-2 Robotic PCF S

Robotic PCF S Machine Part Numbers			
MED11130	MED11131	MED11132	MED11133

Quantity	Part No.	Description	Checklist ☒
1	MP18990	Si Robotic Basket	
1	MED1014x	Thermal printer (For country specific version see 2-6-2)	
1	MP21430	Standard PCF Accessory Kit	

2-5-3 Standard Accessory Kit (MP21424)

Quantity	Part No.	Description	Checklist ✓
1	MED8557	Detergent Pick Up Assembly	
2	MED8564	Instrument Organiser	
1	MET129	Water Heater Spanner	
3	HOSE007	Water Inlet Stainless Steel Hose – Red Indicator	
1	HOSE010	Overflow Hose clear PVC reinforced 50mm I/D	
1	MED3020	Drain Hose 2.5m	
1	MED8558	Jubilee Clip 50-70mm	
1	MED1017	Printer Serial Data Cable DB9 Male to Female Straight through	
20	M20003	Straight Hose & Luer (240mm)	
2	MED1246.5.0	Distal Connector box of 10 mixed	
1	SWITCH004	Lid Lock Override Key	
1	SWITCH006	Electrical Cabinet Door Key	

2-6 Additional Accessories

A range of Medisafe approved accessories including replacement parts and consumables, may be purchased from your supplier. The use of these compatible Medisafe approved products will ensure the continued and reliable operation of your machine.

Note: *Using non-approved chemicals, accessories, and replacement parts may cause damage to the machine and could void both your warranty and your guarantee of performance.*

2-6-1 Baskets

Part No.	Description
MED8601	Standard Basket
MP21833	Si Robotic Basket – Including Hose & Luers
MP21104	Xi Robotic Basket – Including Hose & Luers

2-6-2 Printer

Part No.	Description
MED1014B	Thermal printer including power supply, paper and USA plug
MED1014C	Thermal printer including power supply, paper and European plug
MED1014F	Thermal printer including power supply, paper and Australian plug
MED1014G	Thermal printer including power supply, paper and UK plug
MED1014M	Thermal printer including power supply, paper and South Africa plug
MED1014.1	Thermal printer paper (1 x 25m roll)

2-6-3 Approved Chemicals

Part No.	Description
MED7701	EDA+ 10L Bottle
MED8037	3Ezyme 10L Bottle

2-7 Installation Requirements

Machine Position	
Site	Level floor and at least 150mm (6in) away from surrounding walls for ventilation (see section 2-9 for dimensions and clearances). There should be enough free space provided near the machine for safe and efficient maintenance in the future.
Ambient Lighting	500 Lux minimum room lighting

Mains Supply		
Cables shall be rated for maximum current of the equipment, meeting the requirements of IEC 60227 or IEC 60245. The SI PCF is supplied with 1.8m (6ft) of screened power cable.		
USA Model MED11121UL (only) Power cable must be wired using a plug and socket.		
For all Other Models Power cable must be permanently installed by wiring directly into a switched wall panel. Under no circumstances should it be wired using a plug and socket.		
Conductor Colour Coding		
380-415V 3~ Models	200-230V 3~ Models	Single Phase Models
MED11120, MED11132 MED11123, MED11133	MED11122, MED11130, MED11121, MED11121UL, MED11131	MED11100 MED11110
Live 1: Brown Live 2: Black Live 3: Grey Neutral: Blue Earth: Green/Yellow	Live 1: Black Live 2: Black Live 3: Black Earth: Green/Yellow	Live: Brown Neutral: Blue Earth: Green/Yellow
The cable must be protected with a 3phase Residual Current Device (RCD) and Miniature Current Breaker (MCB). The RCD and MCB shall only be used to supply this equipment.		
The disconnect switch must: - Isolate all poles simultaneously - Be lockable in the off position - Comply with standards IEC/EN 61058-1 and IEC 60447 (creepage and clearances for 4kV transient voltage) - Be situated close to the equipment for ease of accessibility, and in a position where the operator can turn it off in an emergency without leaning over the machine. - Marked as the disconnection device for this equipment - Disconnect device off-position should be clearly marked (O) and the on-position should be marked (I)		
 To avoid risk of electric shock, this equipment must only be connected by a fully qualified electrician and to a mains supply with a protective earth.		
Supply Voltage	See Section 5-1	
Position of supply	<1.8m from power cable exit. (<i>Rear lower left of unit</i>) If >1.8m please advise	
Electro Magnetic Compatibility (EMC)	Medical electrical equipment needs special precautions regarding EMC and shall be installed according to the EMC information provided in the Appendix	

Water Supply	
Water Hardness (CaCO ₃), Quality & Purity	<125ppm with water quality and purity tested and approved for Disinfection as per EN ISO15883-1:2009 (<i>item 6.4.1 and 6.4.2</i>)
Pressure	2 – 5 bar (30 – 70 <i>psi</i>) for all water supplies
Flow Rate	12 – 30 l/m (3 – 8 <i>US gal/m</i>)
Temperature:	Cold Water 5 – 30°C (41 – 86°F)
	Hot Water 50 – 80°C (122 – 140°F)
	RO Water 5 – 80°C (41 – 140°F)
Connection	1x shut valve with ¾in BSP male thread for hose tail (<i>Hot water</i>)
	1x shut valve with ¾in BSP male thread for hose tail (<i>Cold water</i>)
	1x shut valve with ¾in BSP male thread for hose tail (<i>RO water</i>)
Position	Within 1m (40in) of proposed installation

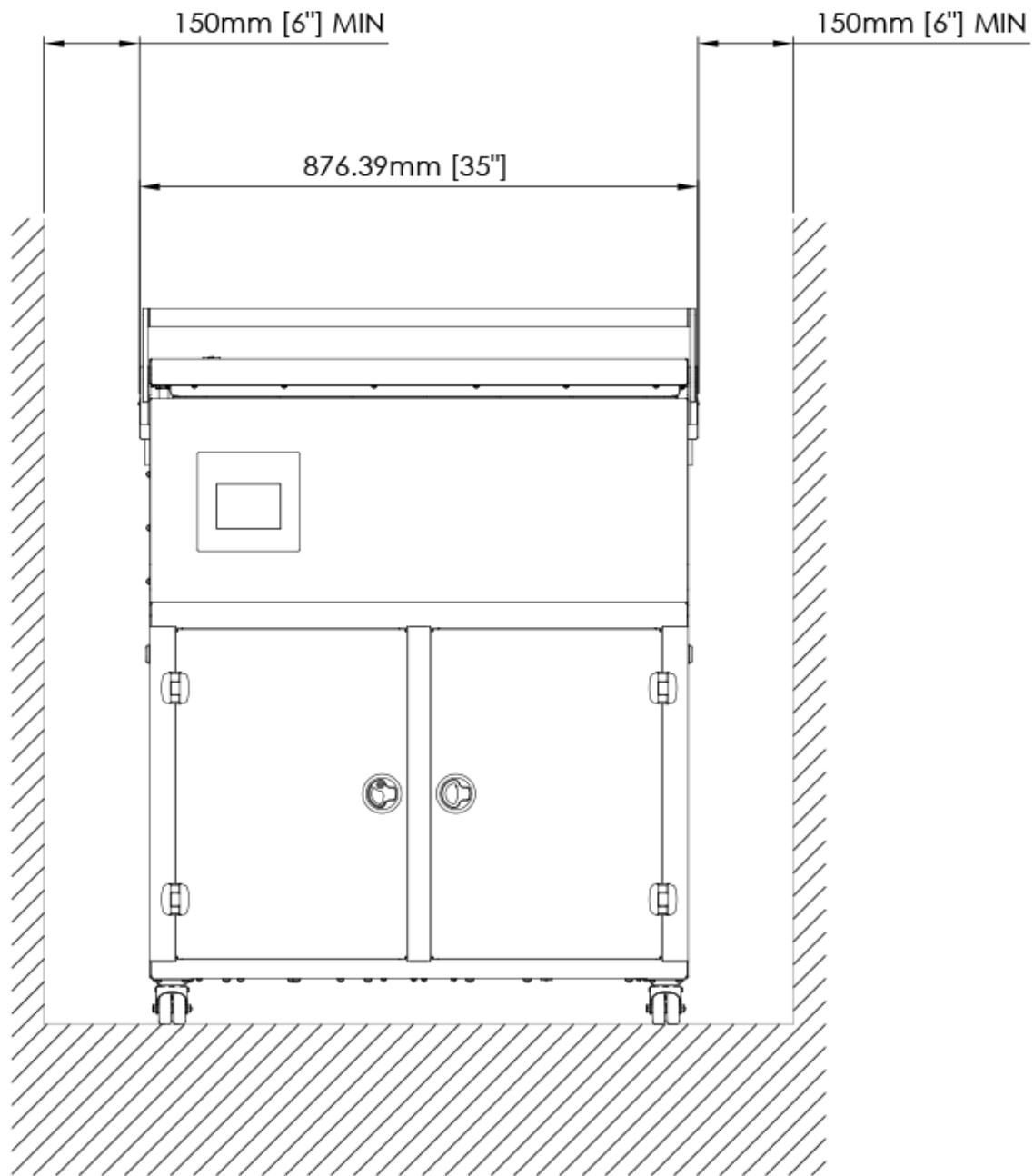
Drainage System	
Type	Pumped
Drain Connection	19mm (¾in) hose tail outlet from machine
	Drain must fitted with suitable traps
	No Loops in the drain hose, cut the hose to required length
Position	Drain entry and the entire drain hose must less than 500mm (20in) above ground level sited at the rear middle of the machine Drain gulley pipe ID must be at least 100mm (4in) to conform with ISO15883
Capacity	> 30ltr/m (8 <i>US gal/m</i>)
Overflow	48.3mm (1.9in) OD outlet from machine – into the same gulley as the drain The overflow hose connection to the main drainage system must not be airtight
Effluent Temp	95°C (203°F)

Printer	
Dimensions	W:230mm (9in) x D:280mm (11in)
Position	Above or to the side and at least within 1m (40in) from the machine, where it will not be affected by spillage, leakage or condensation from the equipment
Supply Connection	90 - 230Vac 50/60Hz (<i>single phase</i>)
Position of printer power supply	Within 1m (40in) from the machine, where it will not be affected by spillage, leakage or condensation from the equipment

2-8 Connecting the SI PCF

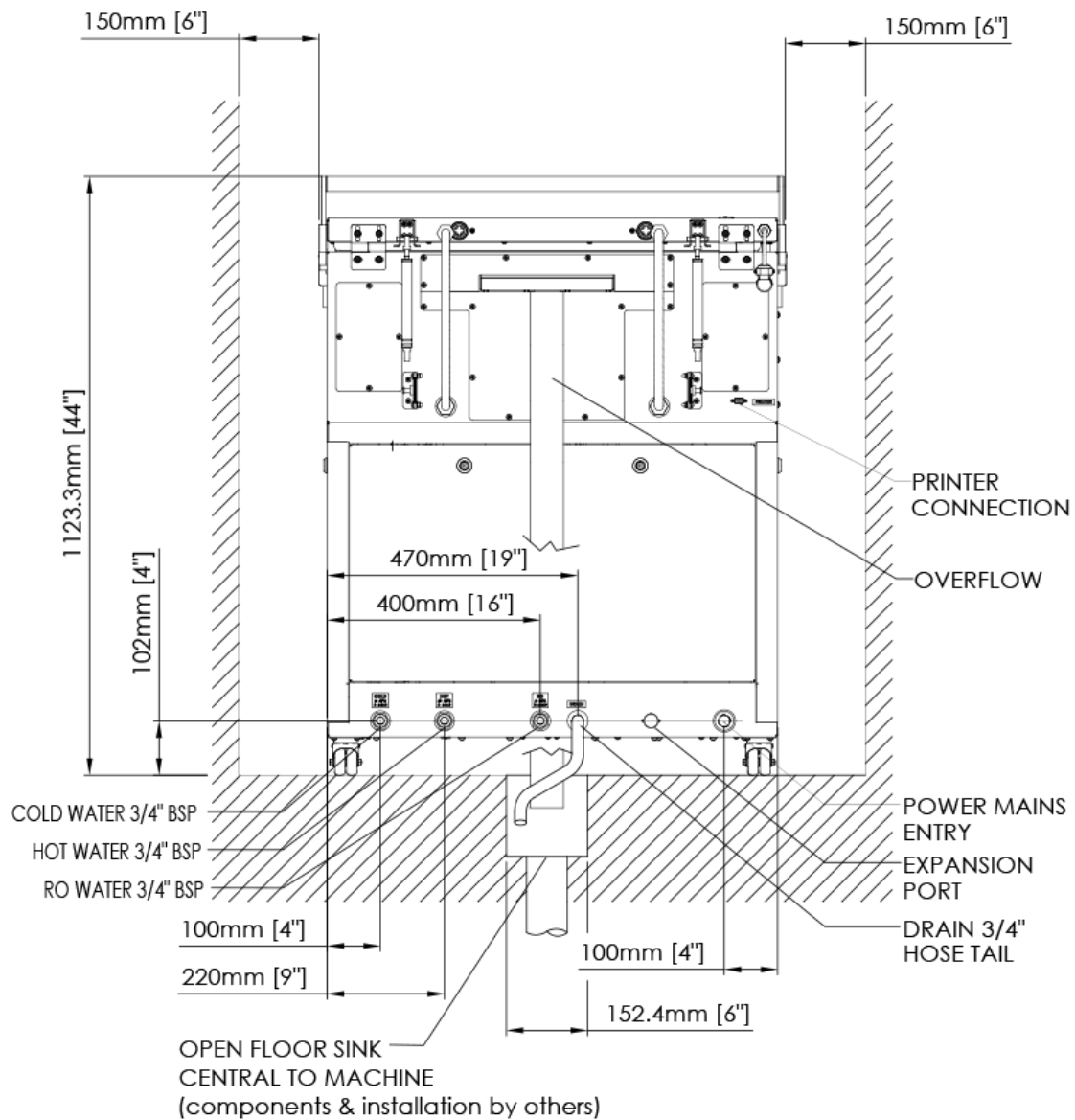
Note: Medisafe (UK) Ltd. recommends this product be installed & commissioned by Medisafe (UK) Ltd (or suitably qualified personnel).

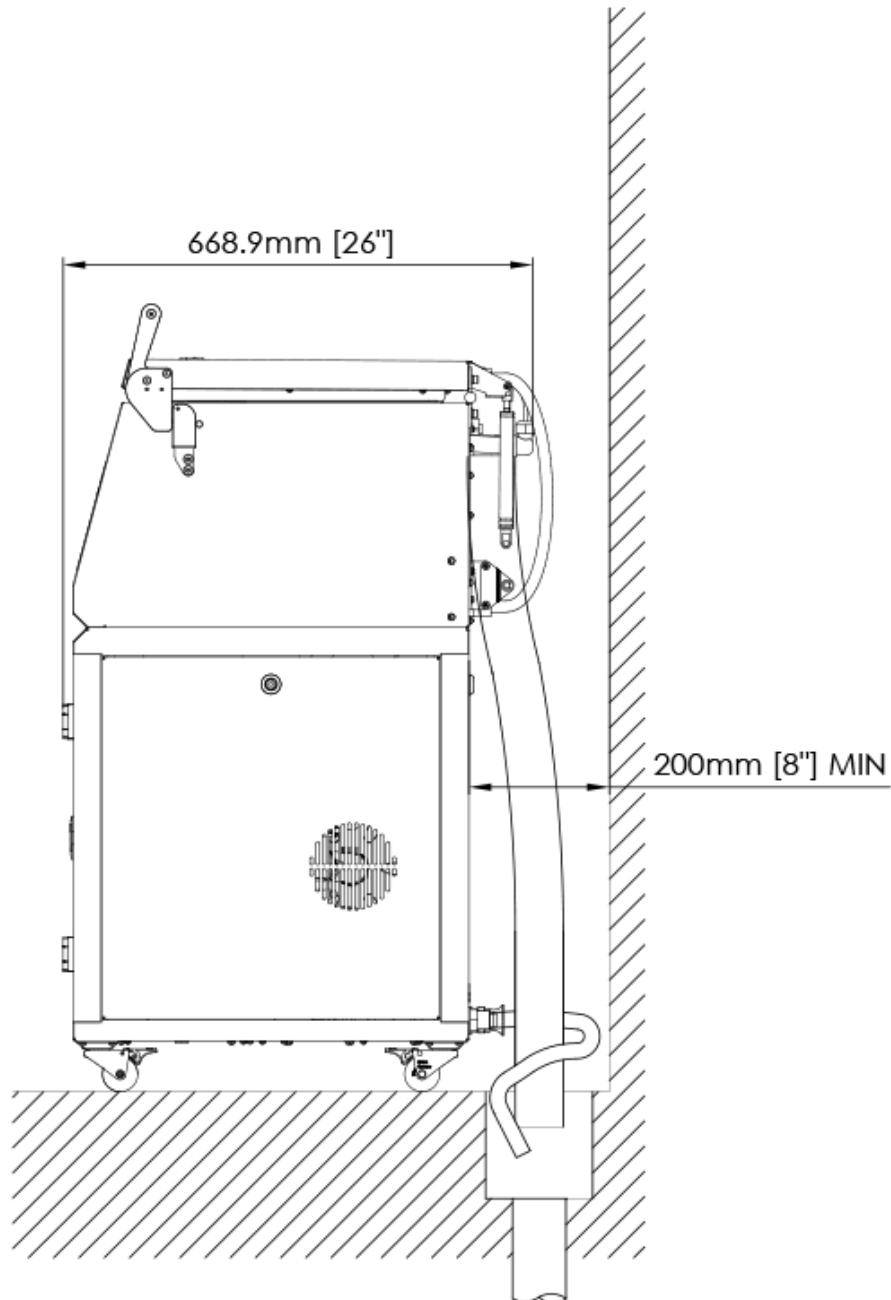
1. Unpack the machine and position it within 1m of the mains power supply, drain, and mains water supplies.
2. Remove any protective packaging and loose items from inside the wash tank.
3. Identify the grey plastic, convoluted drain hose supplied with the unit. Connect the small end of the hose to the $\frac{3}{4}$ " drain hose tail at the lower rear of the unit.
4. Secure the drain hose to the machine using the supplied jubilee clip.
5. Connect the large end of the drain hose to the site drain, cutting to length as required.
6. Identify a stainless steel water hose supplied with the unit. Ensure the seal in the hose end is in place and screw the elbow connector onto the cold-water inlet at the lower rear of the unit.
7. Connect the straight end of the hose to a suitable cold water supply.
8. Repeat for the hot water supply.
9. Repeat for the RO water if this has been made available on site.
10. Turn on the water supplies and check for leaks.
11. Connect the machine to the electrical mains supply (see section 2-7).
12. Carry out the commissioning procedure defined within the SI PCF Service Manual.

2-9 Installation Drawings**2-9-1 Front View**

2-9-2 Rear View Showing Services

OPTION 1 DRAIN CONFIGURATION (PREFERRED)

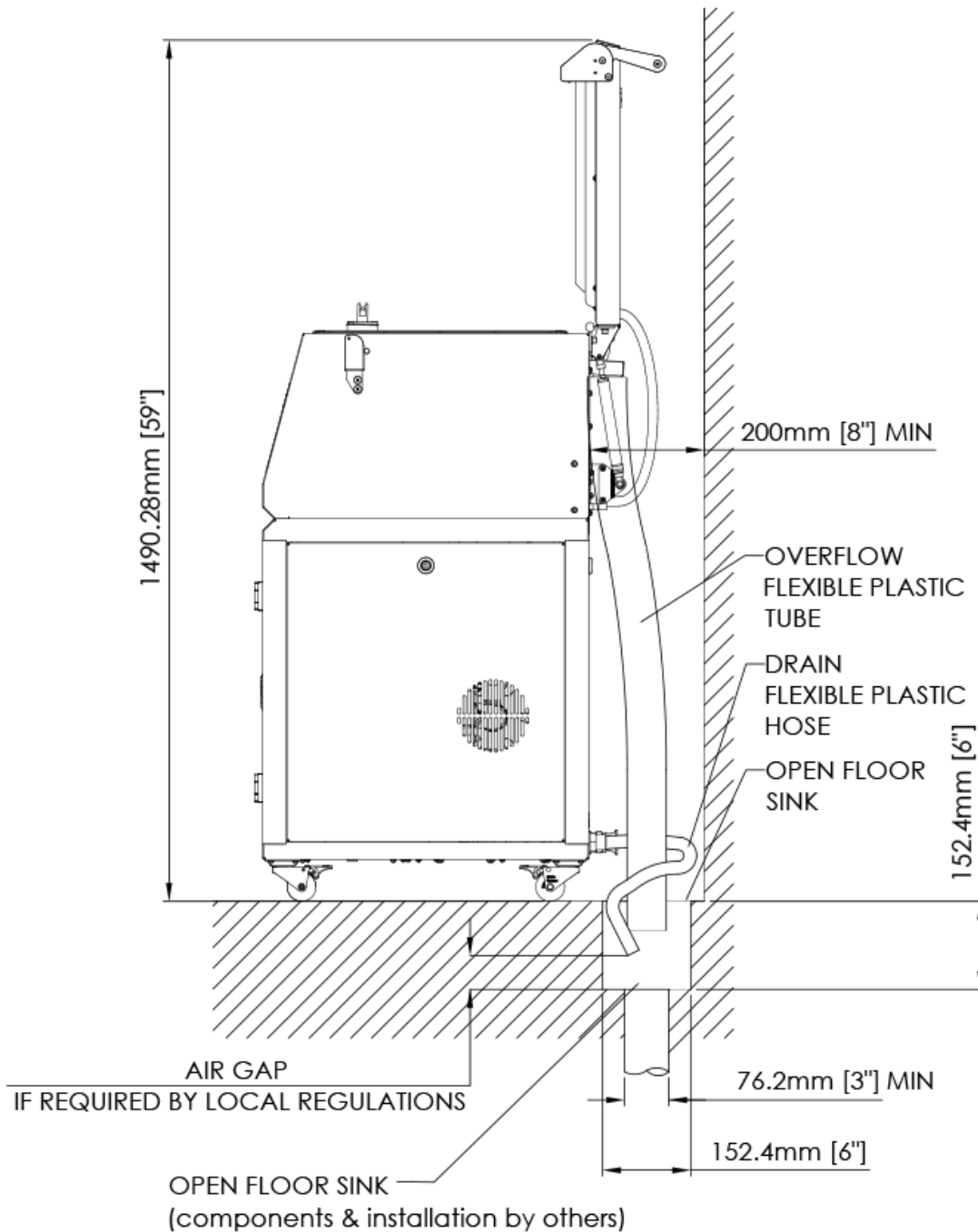


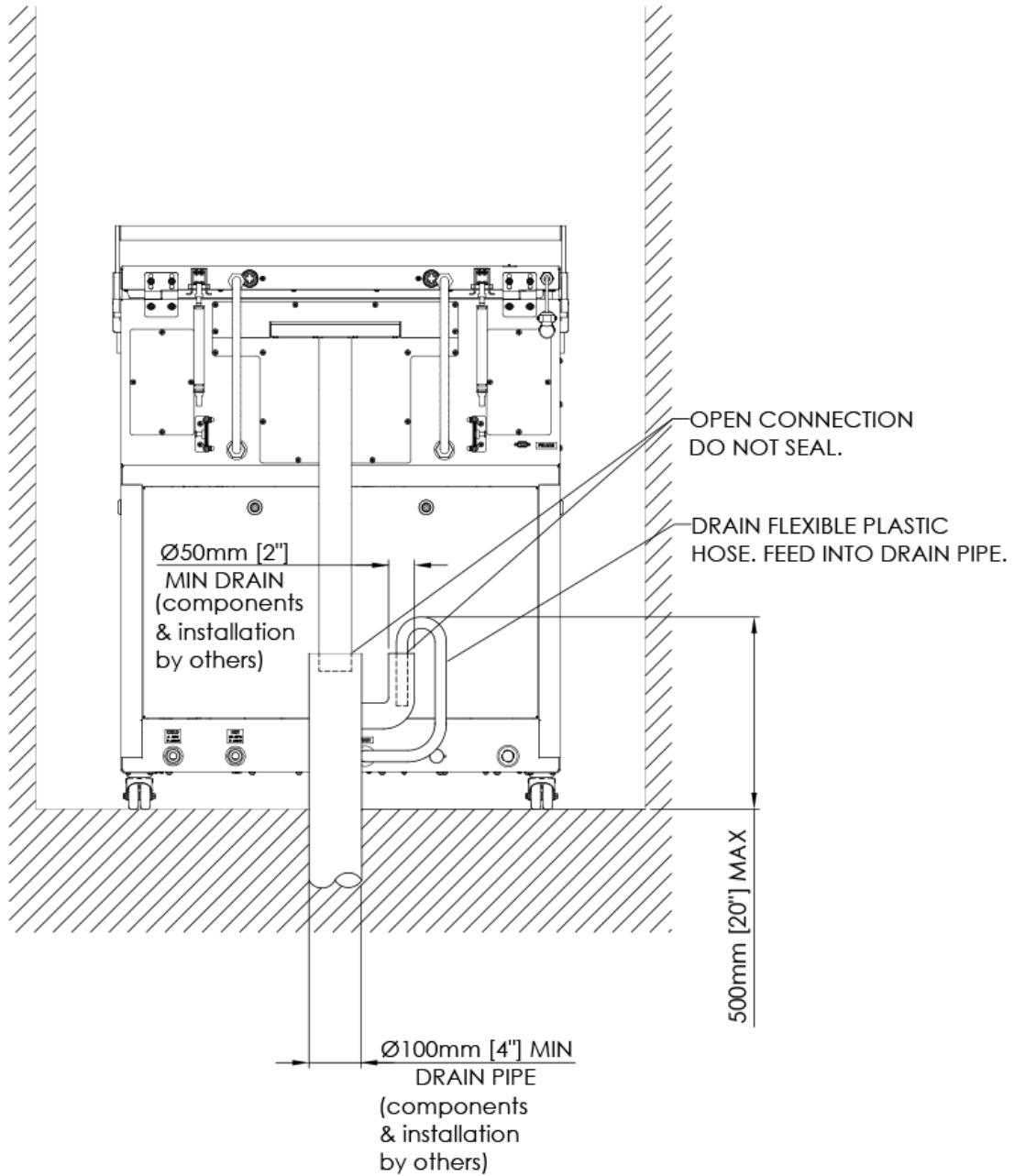
2-9-3 Right Side View Lid Closed**OPTION 1 DRAIN CONFIGURATION**
(PREFERRED)

2-9-4 Right Side View Lid Open

OPTION 1 DRAIN CONFIGURATION

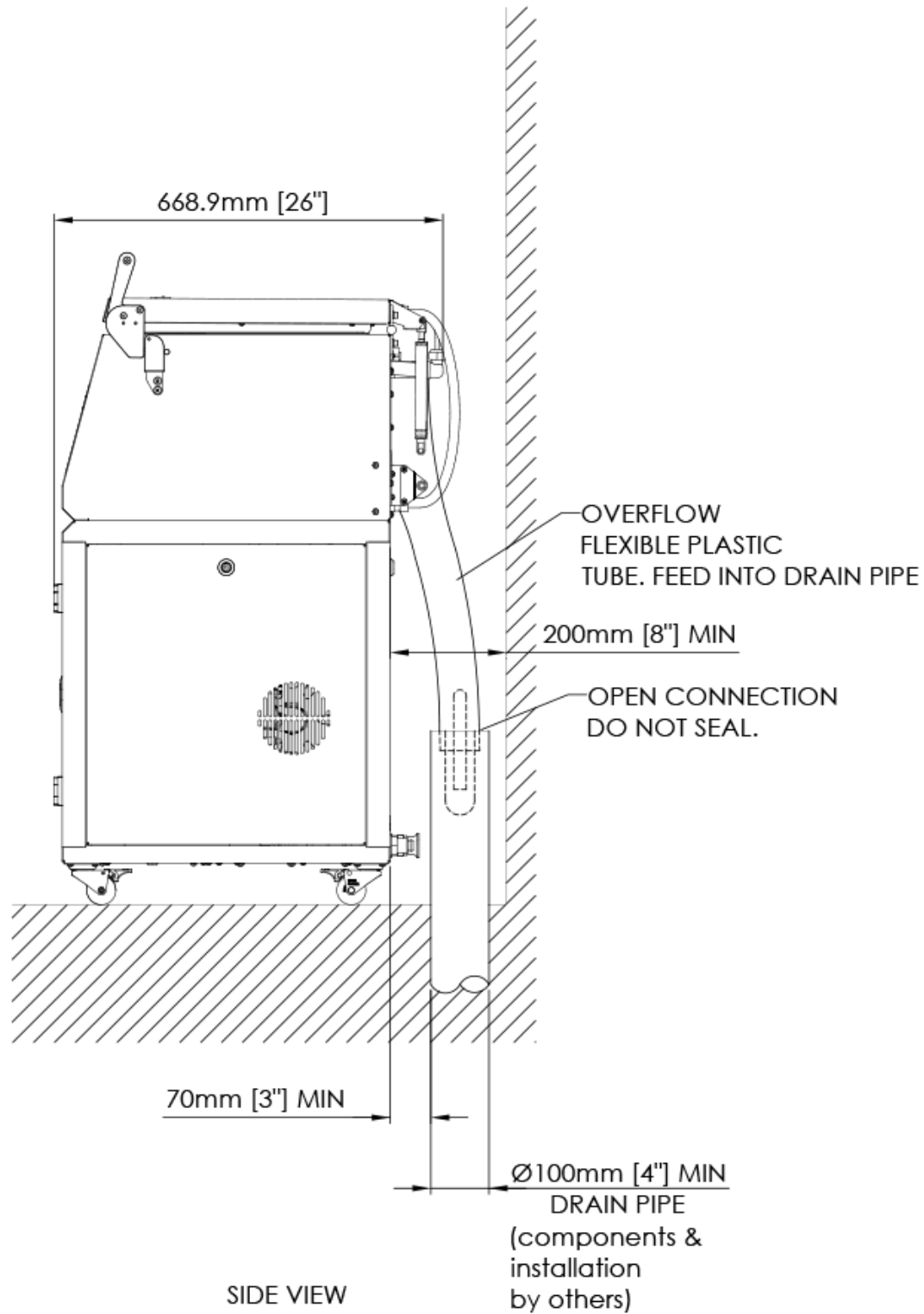
(PREFERRED)



2-9-5 Rear View Alternative Drain Connection**OPTION 2 DRAIN CONFIGURATION**

2-9-6 Right Side View Alternative Drain Connection

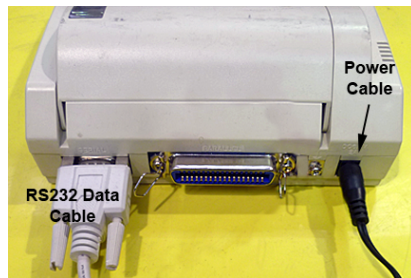
OPTION 2 DRAIN CONFIGURATION



Connecting to the RS232 Port

2-10 Thermal Printer

1. Identify the RS232 Data Cable supplied, and plug the correct end into the socket located at the lower right hand side at the rear of the unit.
2. Connect the other end of the RS232 data cable into the connector on the rear of the thermal printer.



3. Plug the printer power supply cable into the rear socket of the printer, and connect the mains power cable into a suitable mains supply outlet, then switch on the printer.

Note: When the printer paper shows red stripes, this indicates the paper is about to runout, and must be replaced. Once the paper has been changed press the online button, the green led will illuminate and printing will resume.

The printer can store more than 10 cycles in memory when the paper has run out. If the power is not removed when changing the paper, the stored cycles will be printed after the paper has been changed.

2-11 Data Logging PC

Wash cycle data is sent from the serial port to a printer, however, as an alternative data may be sent to a logging device or computer via the serial port using a serial data logging program of your choice.

Note: Only IEC/EN60950-1 certified equipment should be connected.

Connect a suitable RS232 Null modem cable between the data port on the rear panel and a COM port on your PC. Run your serial data logging program, ensuring it is configured in the following manner:

- Baud Rate – 19200bps
- Data Bits – 8
- Parity – none
- Stop Bits – 1
- Flow Control – none
- Handshaking – off
- Buffer size > 500
- Append line feed to cartridge return

Intentionally blank



3. Operation

User Manual



3-1 Menu

The SI PCF is controlled using a touch screen menu. The scroll ⏪ ⏩ arrows are used to cycle through the menu pages.



Menu Functions

	Start	Start the automated cycle sequence
	Wash Program	Set the selected wash program
	Chemical 1	Prime chemical pump 1
	Chemical 2	Prime chemical pump 2
	Clock	Set the time and date
	Data Logging	Download logged cycle data onto a USB Flash Drive
	Supervisor Menu	View and Edit Program Parameters
	Information	Serial number, cycle count and software version

Note: When the SI PCF has been idle for 10 minutes the screensaver will start, touch the display to exit.

3-2 Power Up

Turn on the power to the machine using the isolation switch on the wall.

When the machine is turned on, it conducts a Power-On Self-Test (POST) to ensure the machine is ready for use.

This process takes a few seconds to configure the machine and check the basic operation of the control system, memory and sensor interfaces.



3-3 Authorisation code

This is an optional feature, which can be enabled by a service engineer. When enabled, the user is required to enter a four-digit PIN number to unlock the user control panel. A valid PIN entry identifies the user and their operator number is shown on the cycle printout. There are 80 operator numbers each with a unique PIN number, see Appendix 6-8 for details.



3-4 Setting Time & Date

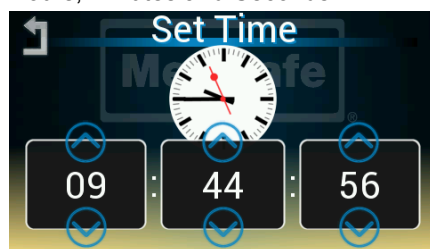
The time and date must be set correctly to ensure the accuracy of the cycle records, and **MUST** be periodically checked by the user. There is no automatic provision for daylight saving hours. While the machine is off, a backup battery maintains the time and date.

3-4-1 Set Time

1. Use the scroll ⏪ ⏩ arrows to cycle through to the clock icon



2. Press **Set Time**
3. Use the ⏶ ⏷ arrows to adjust the Hours, Minutes and Seconds



4. Press ⏶ to return to the main menu

3-4-2 Set Date

1. Use the scroll ⏪ ⏩ arrows to cycle through to the clock icon



2. Press **Set Date**
3. Use the ⏶ ⏷ arrows to adjust the Date, Month and Year



4. Press ⏶ to return to the main menu

3-5 Selecting a program

The SI PCF is installed with six pre-programmed wash cycles during manufacture. When starting a cycle, the machine will use the currently selected program. To change the selected program, prior to initiating a cycle:

1. Use the scroll ⏮ ⏭ arrows to cycle through to the Wash program icon
2. Change the selected program with the + and – buttons



3-5-1 Standard Program Parameters

Parameters	Units	Program Number					
		Standard Wash Cycle	Re-Wash Cycle	Heavy Wash Cycle	Standard Disinfect Cycle	Heavy Disinfect Cycle	Intense Disinfect Cycle
		P1	P2	P3	P4	P5	P6
Pre-wash Time	Minutes	3	0	3	3	3	3
Wash Chemical 1	ml	360	360	360	360	360	360
Wash Temperature	°C	40	40	40	40	40	40
Degas	Minutes	3	3	3	3	3	3
Wash Time	Minutes	5	10	20	5	10	20
Rinse Temperature	°C	60	60	60	60	60	60
Rinse Time	Minutes	2	2	2	2	2	2
Disinfection Temperature	°C	0	0	0	90	90	90
Disinfection Time	Minutes	1	0	1	1	1	1
Typical Total Cycle Time	Minutes	40	10*	50	55	60	70

*Per Re-wash, see section 3-11-10

3-5-2 Robotic Program Parameters

Parameters	Units	Program Number					
		Standard Wash Cycle	Re-Wash Cycle	da Vinci Wash Cycle	Standard Disinfect Cycle	Heavy Disinfect Cycle	da Vinci Disinfect Cycle
		P1	P2	P3	P4	P5	P6
Pre-wash Time	Minutes	3	0	3	3	3	3
Wash Chemical 1	ml	360	360	360	360	360	360
Wash Temperature	°C	40	40	40	40	40	40
Degas	Minutes	3	3	3	3	3	3
Wash Time	Minutes	5	10	20	5	10	20
Rinse Temperature	°C	60	60	60	60	60	60
Rinse Time	Minutes	2	2	2	2	2	2
Disinfection Temperature	°C	0	0	0	91	91	91
Disinfection Time	Minutes	1	0	1	3	3	3
Typical Total Cycle Time	Minutes	45	10*	60	65	70	80

*Per Re-wash, see section 3-11-10

3-6 Chemical Handling



Warning

Users must read this section prior to any chemical handling.

- Detergents are caustic and can cause adverse effects to exposed tissues. Do not get in eyes, on skin or attempt to ingest by mouth
- Read and follow precautions and instructions on detergent label and in the Material Safety Data Sheet (MSDS) prior to handling chemical, refilling chemical containers or servicing chemical injection pumps and lines
- Wear appropriate Personal Protective Equipment (PPE) whenever handling chemicals or servicing chemical injection pumps and lines. This should include plastic gloves, goggles or full-face visor, and disposable plastic apron
- Wear appropriate PPE whenever removing baskets or parts from cleaning chamber
- In case of body contact with chemical, always follow emergency procedure given in that chemical's MSDS or call emergency services
- Guidelines to be followed in case of emergency caused by chemical contact should be prominently displayed near the machine
- Use a funnel when transferring any chemical from one container to another
- Optional lubricants and any other chemical have to be validated and proven compatible with the PCF by its manufacturer

3-6-1 Chemical Consumption

A 10-litre detergent bottle will give approximately 27 washes.

3-6-2 Chemical Replacement

The right hand door allows access to the chemical storage compartment, where the pickup connections are located.

The machine uses a float switch in the bottle to detect when there is insufficient chemical to run a cycle, prompting the user to replace the bottle. This assembly is inserted into the chemical bottle until the base of the float switch rests on the bottom.

Chemical 1 - Detergent

The Detergent sensor plug and pickup tube connect to the left hand socket and port.

Chemical 2 - Lubricant

The Lubricant sensor plug and pickup tube connect to the right hand socket and port.



Caution

Chemical bottles **must** be connected to the correct port. Otherwise, wash efficiency and/or rinsing will be compromised.

3-6-3 Disposal of chemical containers

For the correct disposal of chemical containers, please refer to the manufacturer's instructions and local regulations.

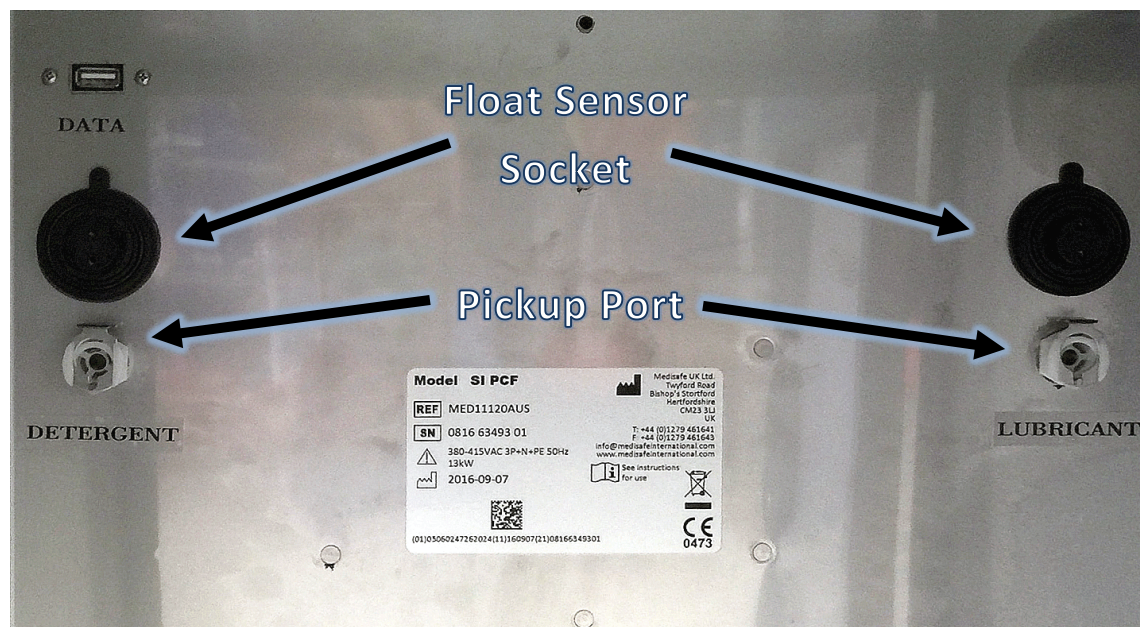
3-6-4 Chemical Priming

When changing an empty detergent bottle, to prevent unnecessary cycle errors the system should be primed to ensure chemical fills the entire hose, from the supply to the tank.

1. Remove the empty container
2. Place the new container in the chemical compartment
3. Place the intake hose in the container, ensure any spillages are cleaned up
4. Use the scroll ⏪ ⏩ arrows to cycle through to the relevant *Prime Chemical Pump* icon ⚠ or ⚠



5. Press **Prime Chem. Pump** to start the chemical pump
6. When chemical can be seen entering the tank, press **Prime Chem. Pump** again to stop the pump



PCF Chemical Cabinet Connections

3-7 Baskets

The SI PCF basket is used to hold the instruments during the wash process. It is easily placed into and removed from the machine, utilising a drop and lock retaining feature. This prevents the basket from moving during operation, and ensures maximum irrigation pressure.

The standard basket is equipped with twenty ports for irrigation of up to 20 hollow instruments. These are divided equally between each corner to prevent crossovers or shadowing of instruments.

3-7-1 Basket Removal

To remove the basket, open the lid of the machine and pull the handles up to disengage the latch, then lift from the machine.



3-7-2 Basket Insertion

Lower the basket into the machine pushing down on the handles.



Push down until the side latches engage on both sides of the tank as shown.



3-8 Instruments

The basket ports are divided equally between each corner to prevent crossovers or shadowing of instruments.

When selecting Instruments for the SI PCF:

- **Always** confirm compatibility with the instrument manufacturer.
- **Always** follow the manufacturer's instructions if processing instruments with special characteristics e.g. fibre optics or rigid optics.
- Whether pre or post processing instruments, **Always** follow the manufacturer's instructions.

3-8-1 Instrument Loading Precautions

When loading instruments into a basket observe the following precautions:

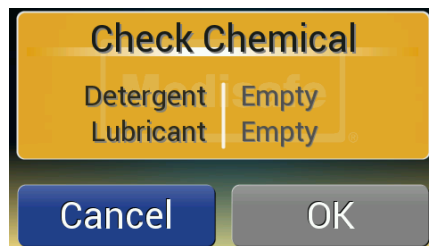
- **Do not** drop items into the wash tank as this could damage the ultrasonic transducers.
- **Do not** place items directly into the wash tank or allow them to make contact with the tank sides
- **Do not** load basket with instruments pointing at the lid
- **Do not** overload the basket, maximum load of 10kg (22lbs)
- **Do not** allow Luer pipes to protrude from the basket
- **Do not** connect more than ten instruments to the Si Robotic Basket as this will reduce the water pressure and compromise effective cleaning.
- **Do not** connect more than six instruments to the Xi Robotic Basket as this will reduce the water pressure and compromise effective cleaning.
- **Always** attach tubing to a suitable size distal connector for instruments being cleaned or to a quick connect port if the instrument has one
- **Always** open box jointed instruments
- **Always** ensure taps are open on cannulated instruments
- **Always** disassemble instruments that are designed to be taken apart
- **Always** attach at least 1 Luer pipe to each basket manifold if cannulated instruments are not being cleaned, this will aid water circulation

3-9 Starting a Standard Instrument Cycle

1. Confirm program selection (to change see section 3-5)



2. Press **Load Instruments**
3. If there is insufficient chemical to complete the cycle a warning will be shown:



Replace chemical(s) (see section 3-6-1) and press OK to continue, or press **Cancel** to abort the cycle start

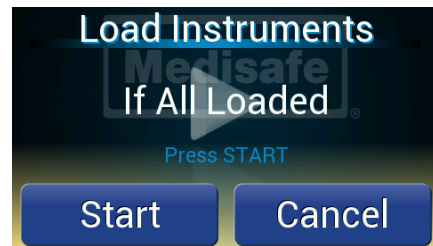
4. Open the lid
5. Remove the basket from the machine
6. Load instruments into the basket
7. Insert the basket into the machine
8. Lower the basket into the machine, pushing down on the handles.



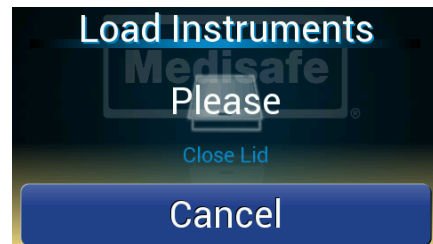
9. Ensure the basket is locked into position by pushing it down until the side latches engage on both sides of the tank



10. Press **Start** to confirm instrument loading complete



11. Close the lid and firmly push down on the handle to engage the lock, and the cycle will begin



Note: The lid has a tight seal and an interlock, which requires the lid to be fully down and latched before the cycle can start (the red interlock switch should be in the locked position).

3-10 Starting a Robotic Instrument Cycle

3-10-1 Manual Pre Wash

Always follow the manufacturer's instructions.

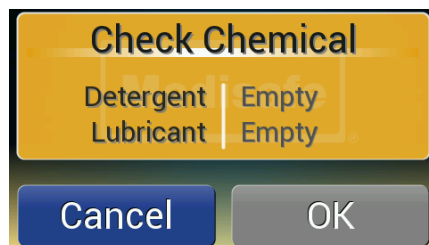
1. Scrub the outside of the entire instrument using running water with a clean, soft, nylon bristled brush, paying special attention to the instrument tip. Move the instrument wrist through its full range of motion while scrubbing
2. Thoroughly rinse the entire instrument especially the instrument tip

3-10-2 Instrument Loading

1. Confirm program selection (to change see section 3-5)



2. Press **Load Instruments**
3. If there is insufficient chemical to complete the cycle a warning will be shown:



Replace chemical(s) (see section 3-6-1) and press **OK** to continue, or press **Cancel** to abort the cycle start

4. Open the lid
5. Remove the basket from the machine

6. Load instruments into the Si or Xi Robotic Basket depending the type to be cleaned:

Connect the instrument to the Medisafe Robotic basket **ONLY**. This basket is clearly marked as 'Sonic Irrigator'.

7. Attach the 'Slip Luer' end of the Medisafe connection tubing to the main flush port of each instrument by firmly pushing to ensure that the Luer is seated.

Si Instrument Connection

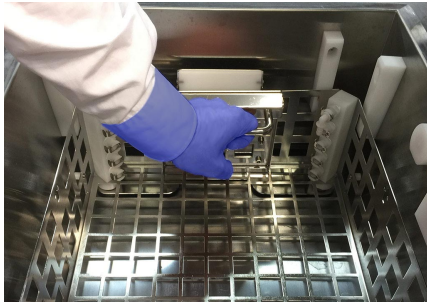
The main flush port is designated by a dark ring and the number 1.



Xi Instrument Connection



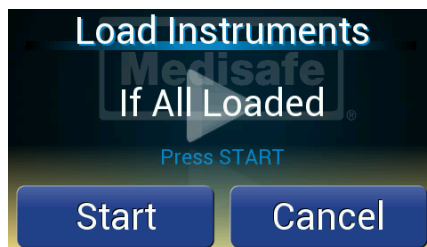
9. Lower the basket into the machine pushing down on the handles.



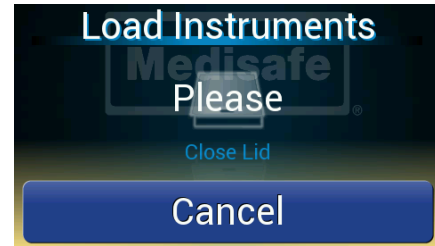
10. Ensure the basket is locked into position by pushing it down until the side latches engage on both sides of the tank



11. Press **Start** to confirm instrument loading complete



12. Close the lid and firmly push down on the handle to engage the lock, and the cycle will begin



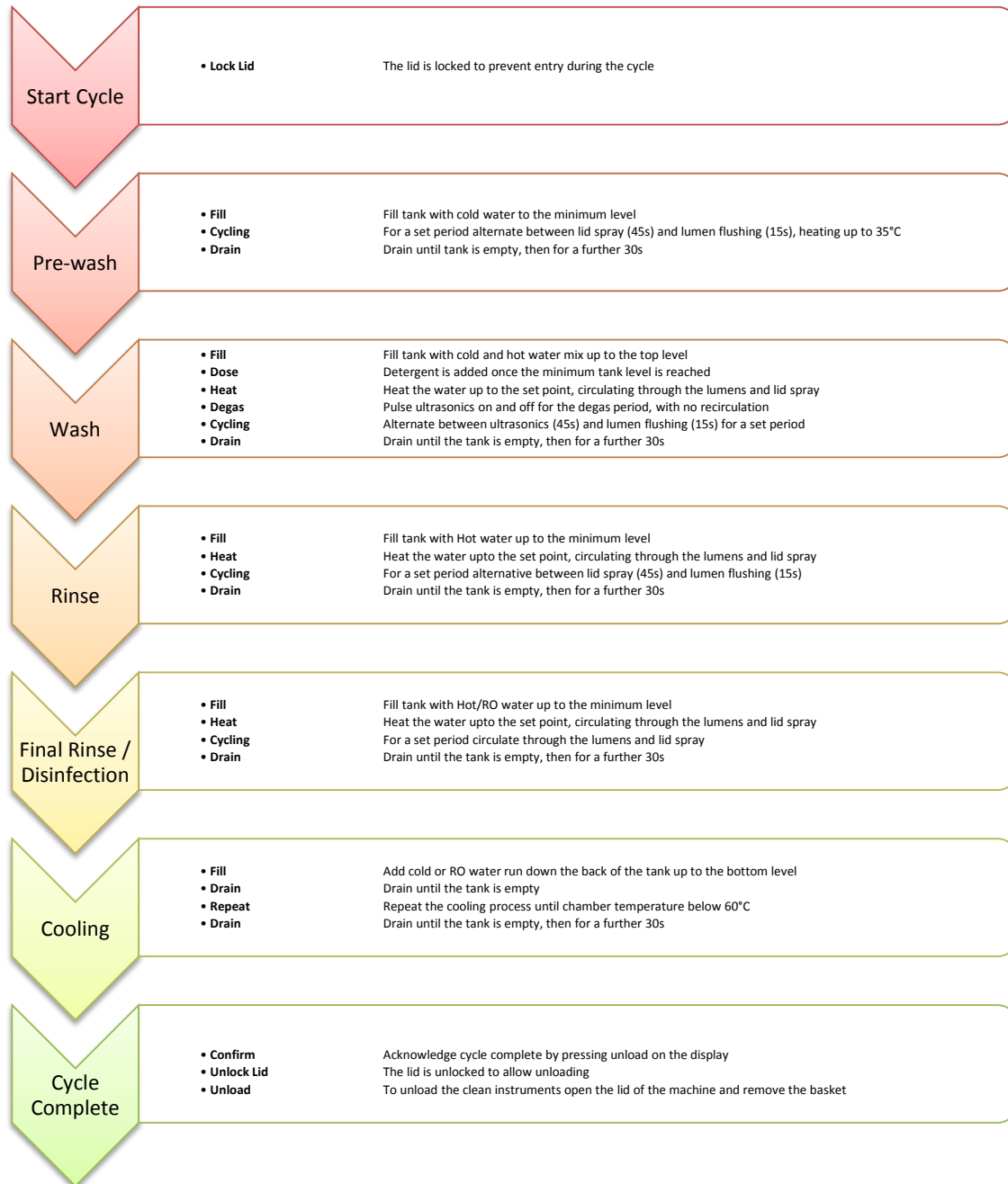
Note: The lid has a tight seal and an interlock, which requires the lid to be fully down and latched before the cycle can start (the red interlock switch should be in the locked position).

3-11 Automated Wash Cycle

The automated wash cycle consists of the stages Pre-wash, Wash, Rinse, Final Rinse/Disinfection and Cooling. Every stage of the cycle is configured by the Program Parameters stored in the machines memory (see section 3-5-1). These parameters allow the cycle to be customised to select the fill water type, skip stages, repeat stages, control temperature set points, set stage duration etc.

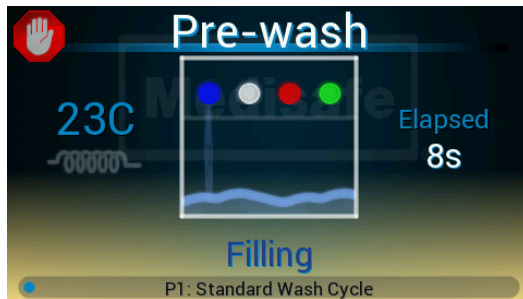
During a cycle, the remaining time for each stage will be shown on the right hand side of the display, and the temperature/pump pressure on the left.

3-11-1 Cycle Process

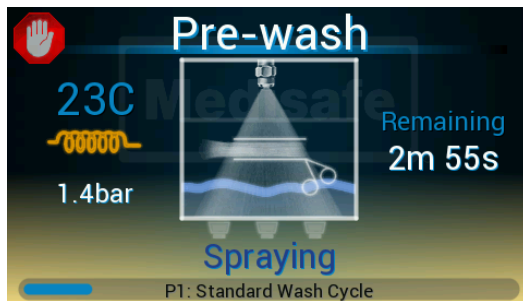


3-11-2 Pre-wash

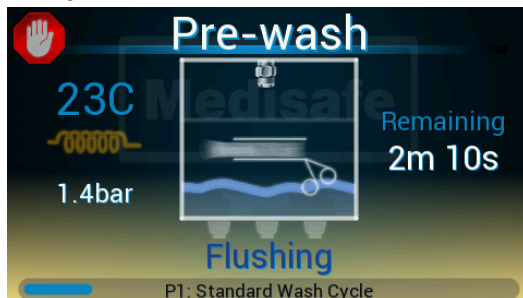
All water in the tank is drained. The machine fills with cold water to the minimum level. During filling for each stage, the spray and irrigation valves are opened, and the pump is operated at least once to ensure all voids are filled.



The machine then washes for a set time, alternating between spraying and flushing.



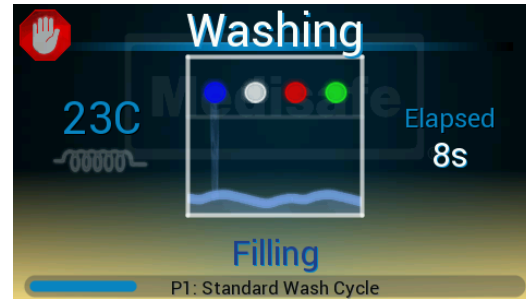
During flushing recirculated water is pumped through the instruments.



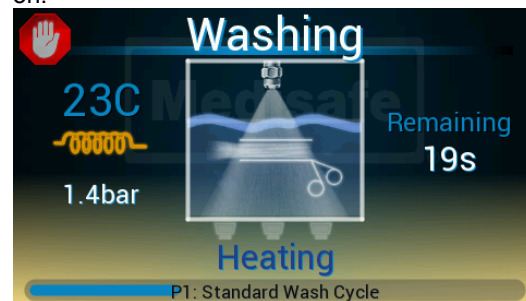
Finally, all water in the tank is drained

3-11-3 Wash

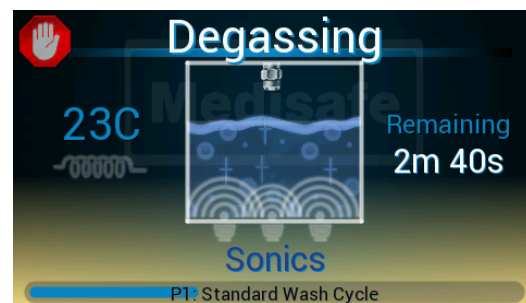
The tank is filled to the top level with a mix of hot and cold water to attain the set temperature. Once the water reaches the mid-level, a quantity of detergent is dispensed into the tank. The pump is pulsed on and off to even out the temperature, fill all cavities, and to mix the chemical thoroughly.



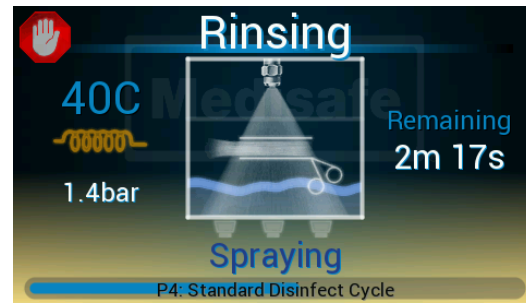
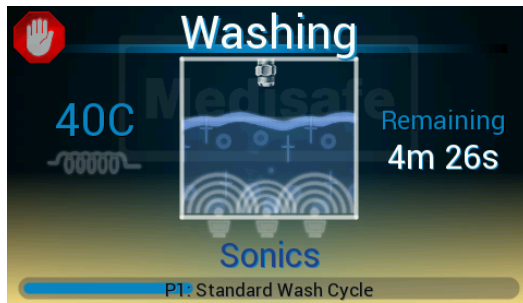
Once the tank is full, if the temperature is below the set point, the water heater will turn on.



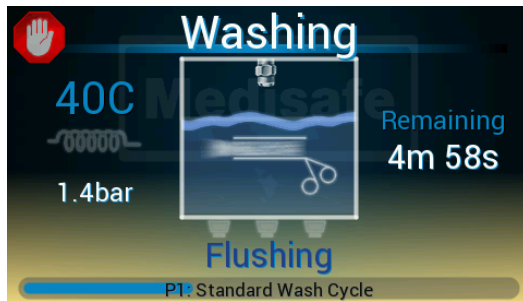
When the set temperature is reached, the ultrasonics degas the tank by pulsing on and off for a pre-defined time to remove any dissolved air.



At the end of the degas period the machine will then alternate between irrigation and *Ultrasonics* for a pre-defined time.

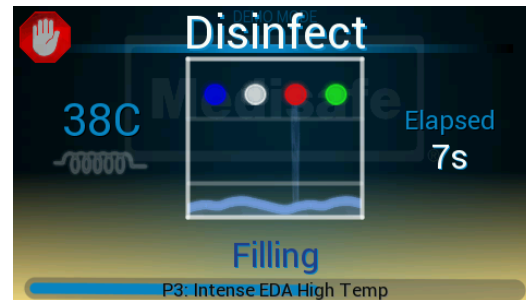


Finally, all water in the tank is drained.



3-11-5 Final Rinse/Disinfection

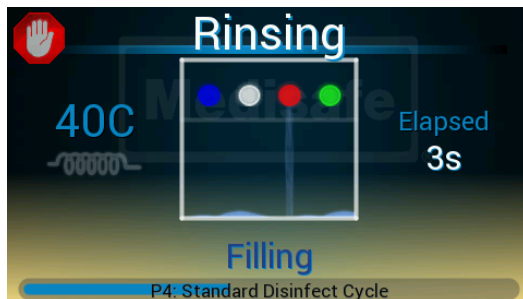
The machine fills with hot water (or RO if fitted) to the minimum level.



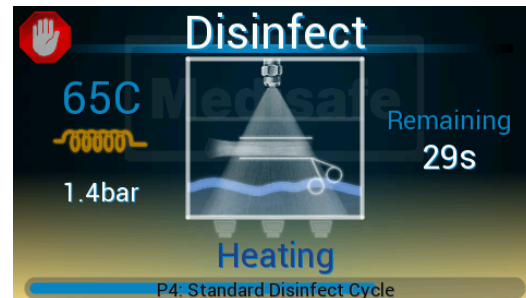
Finally, all water in the tank is drained.

3-11-4 Rinse

The machine fills with hot water to the minimum level.



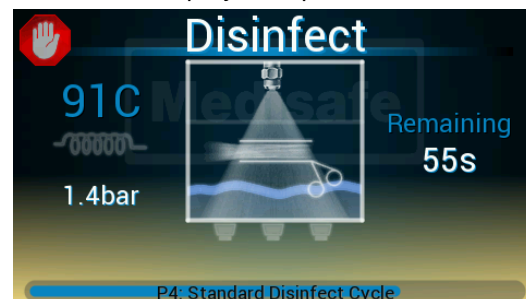
Once the tank is filled, the water heater will turn on to heat the water to the set point.



Once the tank is filled, the water heater will turn on to heat the water to the set point.



When the set point is reached, the machine will *Flush* and *Spray* for a pre-defined time.

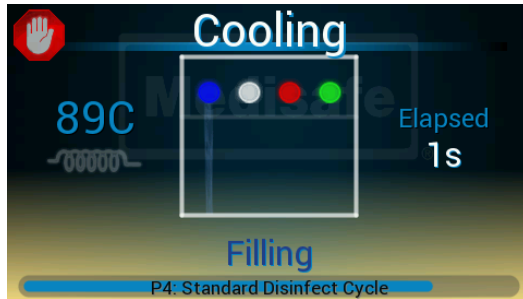


When the set point is reached, the machine will alternate between *Flushing* and *Spraying* for a pre-defined time.

Finally, all water in the tank is drained.

3-11-6 Cooling

On completion of the last cleaning stage, the inside of the machine will be hot. To reduce the water vapour and temperature, cold water is cascaded down the back wall of the tank and into the drain until the chamber temperature is below 60°C (140°F) or ten minutes have elapsed.

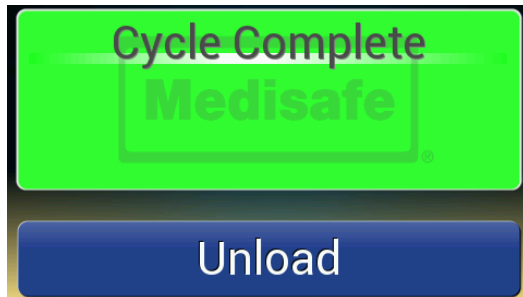


Note: this water does not come into contact with the load.

Finally, all water in the tank is drained.

3-11-7 Cycle Complete

When the cycle is complete, a sound is played.



Confirm cycle record is present and indicates the cycle has completed with no errors.

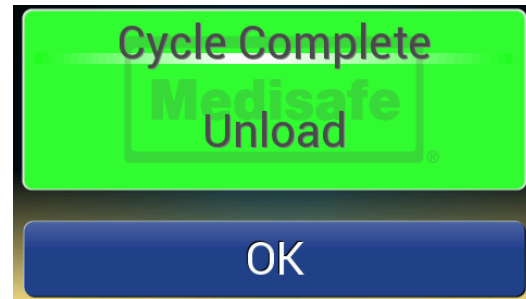
3-11-8 Unload

Open the lid of the machine.

Remove the basket by pulling the handles up to disengage the latch, then lift from the machine.



Press **OK** on the screen to confirm unloading complete



Caution

If any instruments became detached from the Medisafe connection tubing during processing, they should be reprocessed ensuring that the Luer connection is firmly seated.

The machine is now ready for the next cycle



3-11-9 Robotic Instrument Preparation

To prepare the processed robotic instruments for disinfection or sterilisation:

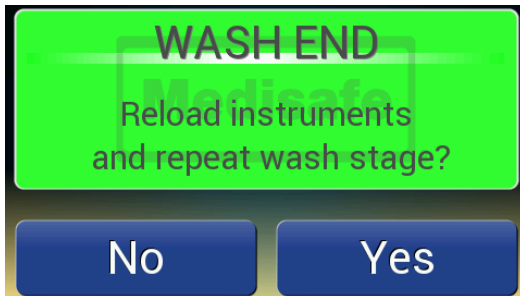
1. Dry the instrument completely. Ensure that all water is emptied from the instrument shaft and main flush port by vertically positioning the instrument with tip up while drying. Dry the outside of the instrument with a lint-free cloth. Air may be blown through all flush ports to facilitate drying.
2. Lubricate the tip and wrist mechanism with a neutral pH, steam-permeable instrument lubricant as per the manufacturer's instructions.
3. Proceed to disinfection after program 3 or sterilisation after program 6.

3-11-10 Re-Wash Cycle

As a water and time saving feature, Program 2 is a re-wash program. This allows the wash water and chemical to be reused. At the end of the wash, the user is allowed to open the lid, add new instruments, and repeat the wash stage using the same water up to ten times.

Note: if the water temperature exceeds the set point by more than 10°C the cycle will be aborted (see section 3-12).

At the end of a wash stage press **Yes** on the screen to reuse the water again.

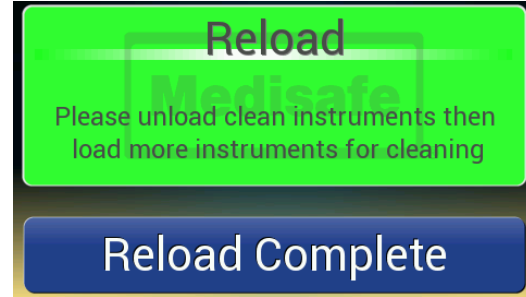


Unload the instruments and load more instruments for cleaning.

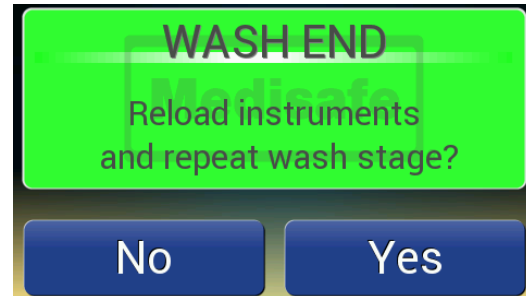


Temperature of the water within the unit can reach 60°C (140°F), take care when opening lid and reloading the instruments.

Press **Reload Complete** on the screen to begin another wash stage



To end the re-wash process, once the wash stage is complete press **No** on the screen to drain the water and end the cycle.



3-12 Cycle Errors

If an unexpected condition occurs during a wash cycle (i.e. low water level, low water temperature, see section 4-1 for a full list) the system will abort the cycle and report an error.

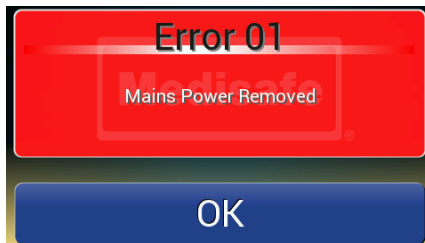


Warning

When an error occurs during a cycle the load may still be contaminated, and will still require processing. Check the printout to see if the cycle completed before the error, if it did not then repeat the cycle to attempt to reprocess the load. If the error persists use another machine or alternative cleaning and disinfection process (according to facility procedure), then contact a service engineer to repair the machine.

If an error occurs:

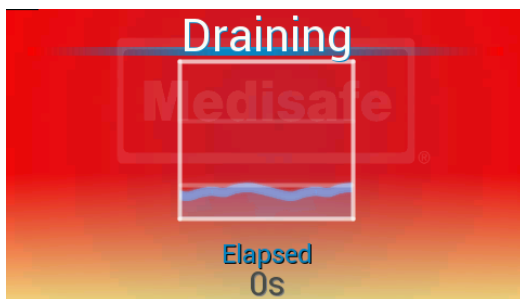
- An audible alarm will sound
- An error code and description will be shown on the display:



- The printer will output the Error code, description, and diagnostic information

Acknowledge the error by pressing **OK**.

If the tank is not empty, the water will be automatically drained to allow access to the load.



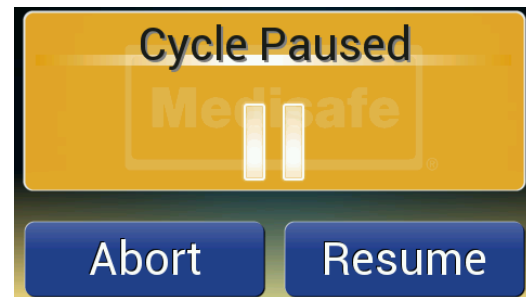
Once the tank is drained, the machine will be reset and return to the main menu.



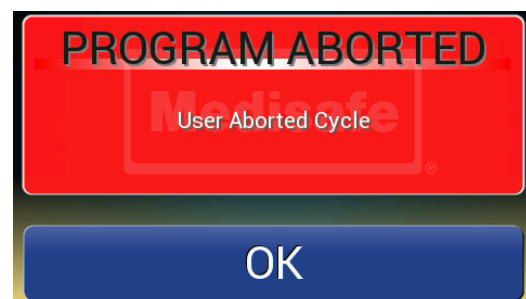
3-13 Aborting a Cycle

While running a cycle in the SI PCF, it may be necessary to end (abort) the cycle operation before scheduled completion, because of a unit problem, wrong load, etc.

To abort a cycle press  in the top left corner. This will pause the cycle, press **Abort** to confirm or press **Resume** to continue the cycle.

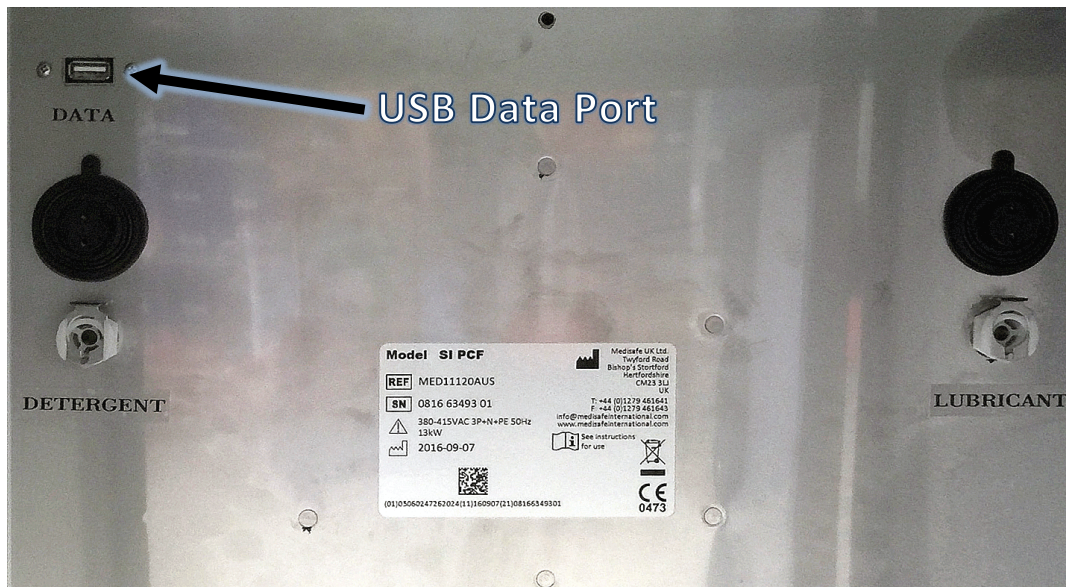


If the cycle is aborted, a cycle error will be generated (see section 3-12)



3-14 Downloading the Cycle Log

The SI PCF contains on board memory, which holds a record of every cycle run on the machine. This Log can be downloaded to a USB flash drive via the USB Data port located in the chemical cabinet on the right hand side of the machine.



3-14-1 Download Logs

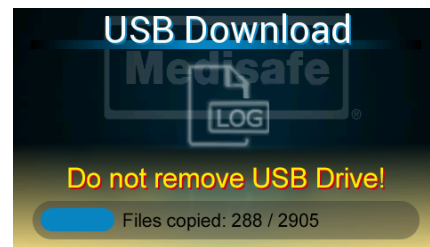
1. Use the scroll ⏪ ⏩ arrows to cycle through to the log icon



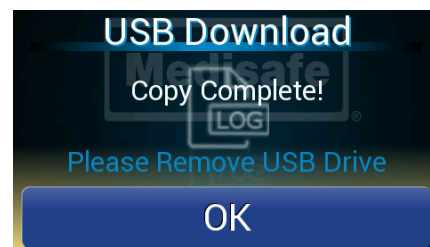
2. Insert the USB flash drive into the USB data port.

Note: the flash drive must be formatted as FAT32.

3. Press **All Logs** to download all cycle logs, or **New Logs** to download the cycle logs since the last download.
4. Wait for the logs to be downloaded to the USB drive. **Do not** remove the USB Drive while downloading, as this could corrupt its contents.



5. Once the log files have been downloaded remove the USB drive and press **OK**



6. A file for each cycle will be stored in the USB drive directory:

MEDISAFE\<machine serial number>\<cycle range>\<cycle number>.txt

3-15 Routine Maintenance

Important safety information:

Always ensure mains power is disconnected.

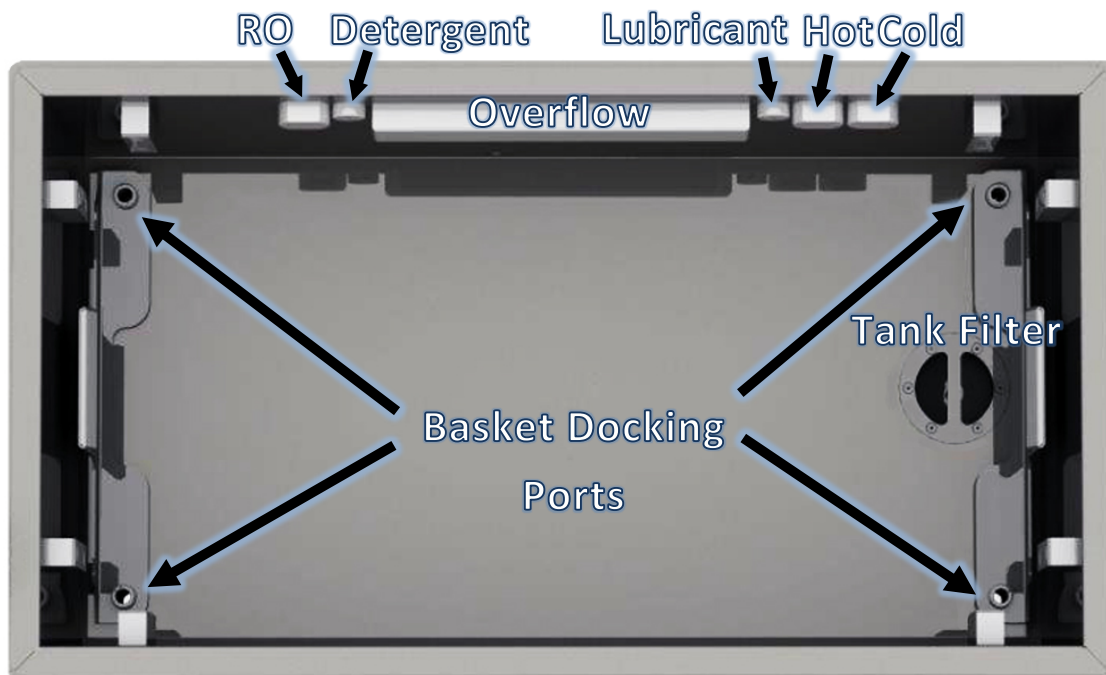
Always adhere to the recommended safety precautions for cleaning products in use.

It is recommended that Personal Protection Equipment (PPE) be worn during loading/unloading, and cleaning or decontaminating the equipment. This must include apron, gloves and eye-protection.

For cleaning internal and external surfaces, a disinfectant cleaner such as Isopropyl Alcohol or a household kitchen cleaner can be used, provided it is marked as a DISINFECTANT cleaner.

In the interests of health and safety, all medical washers should be cleaned on a weekly basis as part of a routine maintenance program. This will ensure the machine is safe for operators and maintenance personnel. To keep your machine operating within its design parameters the following checks must be performed on a regular basis. Please note that completion of these checks is not a substitute for regular servicing and maintenance by a suitably qualified engineer.

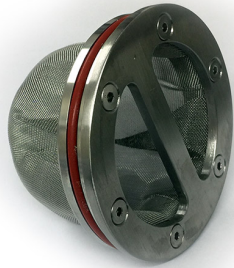
All maintenance procedures should be carried out in a well-lit environment, recommended minimum lighting level is 500Lux.



PCF Wash Tank Connections

3-15-1 Before Every Cycle

1. Visually check that there is enough chemical for the next wash. Replenish as necessary
2. Remove, clean and refit the tank filter, checking the O-ring is still attached and not damaged



3. Check O-rings still attached to the four basket docking ports on the tank



4. Check the wash tank is free from any debris or deposits
5. Check the spray nozzles for blockage
6. Check the condition of basket irrigation port Luer hoses, ensure they are not kinked or ruptured.

**Caution**

If damage is found, please contact a service engineer (see section 1-17).

3-15-2 Daily Checks

1. Automatic control test - select a recent printout and compare parameters with the first printout generated after installation
2. Check that there is sufficient chemical for the days planned use
3. Check and clean all internal surfaces above the water line
4. Check and clean all external surfaces including lid seal
5. Check mains power cord is not trapped, damaged, and the plug is secure in its socket (if fitted)
6. Check lid and lid seal for any damage

**Caution**

If damage is found, please contact a service engineer (see section 1-17).

3-15-3 Weekly checks

1. Carry out the daily checks
2. Check lid opening/closing operation including gas struts
3. Check water hardness of hot and cold water supplies
4. Check water conductivity of final rinse water supply
5. Check condition of mains water supply hoses
6. Visually inspect water and drainage system for leaks
7. Cleaning efficacy test by residual soil detection
8. Run a full decontamination procedure (See section 3-16)

Note: The use of a "Process Challenge Device for Minimally Invasive Surgery" may be required according to your local authority guidelines, and the cleaning indicator manufacturer's instructions

Ref: ISO15883-1:2009

3-16 Decontamination Guide

Decontamination is defined as the cleaning and disinfection of the machine, and is vital to ensure the machine is safe for operators and maintenance personnel.

Important safety information:

Always ensure mains power is disconnected.

Always adhere to the recommended safety precautions for cleaning products in use.

Always work in a well-lit area, recommended minimum lighting level is 500Lux.

It is recommended that Personal Protection Equipment (PPE) be worn during loading/unloading, and cleaning or decontaminating the equipment. This must include apron, gloves and eye-protection.

For cleaning internal and external surfaces, a disinfectant cleaner such as Isopropyl Alcohol or a household kitchen cleaner can be used, provided it is marked as a DISINFECTANT cleaner.

3-16-1 Daily Cleaning/ Procedure

Using a clean cloth or paper towel:

1. Wipe down **all** internal surfaces above the waterline with your disinfectant, including the inside of the lid and around the seals
2. Wipe **all** external surfaces, including around the sides of the doors
3. Remove any trace of cleaner from internal and external surfaces with a clean wet cloth
4. Towel dry

Note: By the nature of its operation, the washer disinfectant's tank is immersed in water during the cleaning/disinfection cycle. Therefore, it should already be clean and disinfected by the end of a cycle.

3-16-2 Full Decontamination

On a weekly basis:

1. Perform the daily cleaning procedure
2. Fit luers to all basket port to ensure they are open
3. Run Program 6 (see section 3-5 and 3-9)

If the machine has been idle for more than a week:

1. Perform the daily cleaning procedure
2. Fit luers to all basket port to ensure they are open
3. To make a 5% disinfectant solution place 1.2 litres (typically) of non-foaming Sodium Hypochlorite based disinfectant into a shallow heat resistant container. Place the container in the basket (*this prevents it from being drained at the start of the cycle*)
4. Select Program 6 (see section 3-5)
5. Start the cycle (see section 3-9)
6. 30 seconds before the Pre-wash stage finishes, press  to pause the cycle
7. Wait 15 minutes then press **Resume** to continue the cycle
8. Allow the cycle to complete

3-16-3 Pre Transport Procedure

In the unlikely event of a machine having to be returned to Medisafe for any reason, the following procedure must be carried out:

1. Drained and completely empty of fluid
2. All external hoses removed
3. Fully decontaminated prior to shipping, (*irrespective of when it was last cleaned*)
4. Accompanied by the relevant signed Decontamination Certificate (see section 3-16-4)

Note: If due to the nature of any fault present, the unit cannot be run prior to return, the tank/chamber must be decontaminated by hand.

Note: Failure to carry out this procedure will incur an additional charge for a full decontamination.

3-16-4 Decontamination Certificate

Ensure that all items returned to your supplier are disinfected in accordance with the appropriate hospital procedure for equipment of this type.

When returning this product to your supplier, the form must be completed and attached to the outside of the crate/carton. If it is not visible, the courier and/or your supplier can refuse to handle this product.

DECONTAMINATION CERTIFICATE

I hereby certify that the machine referred to in this document by model number and serial number has been disinfected in accordance with Hospital Procedure	
Model No.	_____
Serial No.	_____
Hospital:	_____
Name:	_____
Signature:	_____ Dated: _____



Promoting a Clean and Safe Service



4. Troubleshooting

User Manual



This section of the manual describes the types of SI PCF problems which may occur, and indicates probable causes/corrections.

If the situation cannot be corrected following the Troubleshooting Solutions, repeating the cycle, or if a problem occurs which is not described, then please contact Medisafe. Service charges may be incurred, consult your warranty for details. A trained service technician will promptly place your SI PCF in proper working order.

NOTE: *Never permit unqualified persons to service the system. If a system problem cannot be corrected using this section, please contact Medisafe.*

Calling for Service: First, try to define the situation and determine whether it can be solved (see section 4-1 and 4-2). If the situation cannot be solved, call Medisafe and provide the following information:

- A description of the fault
- Model number
- Serial number
- A copy of the printout showing the error

4-1 Error Messages

Error Code	Error Message	Possible Causes and Solutions
1	Mains Power Removed	Check mains supply to unit was not interrupted during a cycle
2	Chamber Overflow	Switch the machine off then on again, if the problem persists turn the machine and the water supply off and call a service engineer
3	Drain Timeout	Check tank filter clear, ensure drain is not blocked Check that genuine Medisafe chemical is being used (EDA+ or 3E-Zyme®)
4	Chamber Temperature Sensor Mismatch	Repeat cycle
5	Chamber Fill Timeout	Check water supply(s) to the machine are switched on Check water inlet hose(s) for kinks
6	Chamber Opened	Check lid is closed
7	Temperature Set Point Not Maintained	Repeat cycle, if the problem persists call a service engineer
10	Chamber Water Level Low	Check that a non-foaming detergent is being used Check for leaks
11	Chamber Water Heat Rate Low	Repeat cycle Temperature sensor or water heater element failure, please call a service engineer.
13	Chemical Dosing	Check chemical bottle level(s) and replace if required. Check chemical pickup tube is inserted into the chemical container

Error Code	Error Message	Possible Causes and Solutions
14	Chamber Start Temperature too High	Check the Cold water temperature is not above 35°C The chamber has not cooled sufficiently since the last wash. Leave more time between washes for the machine to cool down.
15	Chamber Temperature Out of Range	Switch the machine off then on again
16 17 18 19 51	Level Sensor Invalid	Repeat cycle
20	User Aborted Cycle	Repeat cycle
21	Low Main Pump Pressure	Check tank filter is clear/clean Check Basket is docked properly Check Basket ports are not blocked Check for leaks
22	High Main Pump Pressure	Attach a Luer pipe to at least one manifold to aid water circulation Check Basket is docked properly Check Basket ports are not blocked Check for leaks
23	Temperature Set Point Exceeded	Repeat cycle
39 40 41 43 45 46 47	Sonic Generator Fault	Switch the machine off then on again
42	Maximum Cycle Time Expired	Check water supply flow rate is sufficient Check tank filter clean/clear, ensure drain is not blocked Repeat cycle
44	Sonic Cleaning Water Level Low	Check for visual leaks
49 57 58	Microcontroller Error	Switch the machine off then on again
50	Internal Ambient Temperature too High	Switch the machine off then check for blockages in the ventilation holes Switch the machine on again after an hour
52	Real Time Clock Read Error	Switch the machine off then on again
53	24V Power Supply Voltage Out of Range	Switch the machine off then on again
54	Overfill occurred during cool down process	Check tank filter clear, ensure drain is not blocked Repeat cycle
56	Low Wash Irrigation Pressure	Check tank filter is clear/clean Check Basket is docked properly Check Basket ports are not blocked Check for leaks
59	Unable to Store Cycle Log	Repeat cycle

4-2 Other Faults

Problem	Possible Causes and solutions
<i>Poor Load Cleaning</i>	• Insufficient detergent injected. Contact Medisafe • Check that an approved chemical is being used • Instrument basket is overloaded. Adjust load • Instruments are excessively soiled • Instruments have been left soiled for more than two hours • Verify facility power meets Unit specifications
<i>Water Leaking from Lid Area</i>	• Check instruments are lying flat in the basket and not pointing up at the lid • Check lid seal is undamaged
<i>Excessive Fill Time</i>	• Check incoming water pressure is above 2 bar (29 psi) • Check water inlet valve is not blocked (beware of hot water temperature!)
<i>Low Irrigation Port Flow Rate</i>	• Check all connectors are fully inserted • Clean tank filter • Check basket manifold ports are not blocked • Check tank docked ports are not blocked • Verify facility power meets Unit specifications
<i>No Power to Unit or Display is off</i>	• Installation Main disconnect switch is in the OFF position Turn main disconnect switch to the ON position • Facility power is incorrect for unit. Correct facility power to meet unit requirements • Internal Circuit breaker has tripped, contact Medisafe

Problem	Possible Causes and solutions
<i>Lid will not open</i>	• Installation Main disconnect switch is in the OFF position Turn main disconnect switch to the ON position • To override the lid lock: The lid lock override socket is on the top left of the machines lid: A close-up photograph of the top-left corner of a machine lid. A red circular 'Lid Lock Socket' is visible, with a small red dot next to it labeled 'Unlocked Indicator'. Insert the key into the lid lock socket and turn anticlockwise to override the lock to allow the lid to be opened, as shown below. Two side-by-side photographs of the red lid lock socket. The left image shows the socket in its 'Normal' position with the red handle pointing horizontally. The right image shows the socket in its 'Override' position with the red handle pointing vertically upwards. Normal Override Warning The override key must only be used to gain access when the lid is locked and cannot be opened normally, and the machine is not running a cycle. Warning In the case of an incomplete cycle the load will require to be decontaminated, see section 3-12

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5. Technical

User Manual



5-1 General Specifications

General	
Description	Medical Device Class IIb
Intended Purpose	Internal and external cleaning of surgical instruments, hollow-ware, and associated products
Operating Process	Ultrasonic activity, Spray Ports and Irrigation Ports
Classifications	Class 1 electric shock protection, externally powered No applied parts IP rating – IPX0 (refer to BS EN 60601-1, para 6.3) Not suitable for use in an oxygen rich environment Mode of operation – intended for continuous use
Lid	Locking lid prevents access to wash chamber during cycle
Deluge Wash	Top Spray in lid
Irrigation	With ten ports open each basket manifold outputs produces up to 3 bar (43.5psi) pressure with a flow rate of 50ml/s
Basket Connection	Drop and Lock for easy irrigation connection

User Interface	
Display	TFT Touch Screen

Standard Basket	
Features	Four 5-way manifolds, one in each corner
Din Basket Compatibility	Full DIN Tray Standard to hold instruments (M20044) – Length 484mm (19in) Width 253mm (10in) Height 76mm (3in)
Max Load Size	Length 668mm (26.3in) Width 338mm (13.3in) Height 76mm (3in)
Max Load Weight	10kg / 22lb

Si Robotic Basket	
Features	Four 3-way manifolds, one in each corner
Robot Instrument Capacity	10

Xi Robotic Basket	
Features	Two 3-way and Two 2-way manifolds, one in each corner
Robot Instrument Capacity	6

Ultrasonics	
Frequency	34 to 40 kHz dependant on load
Transducers	20 piezo ceramic
Power	800W
Features	Pulsed Degas
	Auto-tune
	Frequency Sweep
	Reflectasonic Technology

Electrical Supply	
General	Mains supply voltage fluctuations up to $\pm 10\%$ of the nominal voltage; Transient over voltages typically present on the mains supply (Overvoltage Category II). Pollution Degree 2
MED11100 (Standard)	Voltage: 200 - 230VAC (<i>Single Phase + Protective Earth</i>) Frequency: 50Hz Power: 5kW Site Current Capacity: $\geq 18\text{A}$ per phase Site MCB and Disconnect Switch Current Rating: 25A Site Wiring Cross-sectional area: 4mm^2
MED11110 (Standard)	Voltage: 200 - 230VAC (<i>Single Phase + Protective Earth</i>) Frequency: 60Hz Power: 5kW Site Current Capacity: $\geq 18\text{A}$ per phase Site MCB and Disconnect Switch Current Rating: 25A Site Wiring Cross-sectional area: 4mm^2
MED11122 (Standard) MED11130 (Robotic)	Voltage: 200 - 230VAC 3P+PE (<i>Three Phase + Protective Earth</i>) Frequency: 50Hz Power: 10kW Site Current Capacity: $\geq 24\text{A}$ per phase Site MCB and Disconnect Switch Current Rating: 32A Site Wiring Cross-sectional area: 6mm^2
MED11121 (Standard) MED11121UL (Standard) MED11131 (Robotic)	Voltage: 200 - 230VAC 3P+PE (<i>Three Phase + Protective Earth</i>) Frequency: 60Hz Power: 10kW Site Current Capacity: $\geq 24\text{A}$ per phase Site MCB and Disconnect Switch Current Rating: 32A Site Wiring Cross-sectional area: 6mm^2
MED11120 (Standard) MED11132 (Robotic)	Voltage: 380 - 415VAC 3P+N+PE (<i>Three Phase + Neutral + Protective Earth</i>) Frequency: 50Hz Power: 13kW Site Current Capacity: $\geq 18\text{A}$ per phase Site MCB and Disconnect Switch Current Rating: 25A Site Wiring Cross-sectional area: 4mm^2
MED11123 (Standard) MED11133 (Robotic)	Voltage: 380 - 415VAC 3P+N+PE (<i>Three Phase + Neutral + Protective Earth</i>) Frequency: 60Hz Power: 13kW Site Current Capacity: $\geq 18\text{A}$ per phase Site MCB and Disconnect Switch Current Rating: 25A Site Wiring Cross-sectional area: 4mm^2

Water Supply	
Back Siphonage Protection	Integral AB type air gap and weir observing BS EN 1717
Consumption (approximate)	Per cycle stage: • Pre-wash 16lts (4.2US gal) • Wash 50lts (13.2US gal) • Rinse 16lts (4.2US gal) • Disinfection 16lts (4.2US gal) • Cooling 20lts (5.3US gal) Total Per supply: • Cold 41lts (11US gal) • Hot 41lts (11US gal) • RO 36lts (10US gal) Total Cycle 118lts (32US gal) Consumption will vary depending on the cycle selected and the site facilities

Drainage System	
Type	Pumped
Drain Connection	19mm ($\frac{3}{4}$ in) hose tail outlet
Overflow	48.3mm (1.9in) OD outlet
Effluent Temp	95°C (203°F)

Dimensions	
Wash Chamber Liquid Volume	43 Litres (11.5US gal)
Wash Chamber Capacity	69 Litres (18.2US gal)
Wash Chamber Dimensions	Width 750mm (29.5in)
	Depth 365mm (14.4in)
	Height 237mm (9.3in)
Outer Cabinet Dimensions	Width 876mm (34.5in)
	Depth 669mm (26.3in)
	Height Lid Closed 1123mm (44.2in)
	Height Lid Open 1490mm (58.7in)
Shipping Container Dimensions	Width 1060mm (41.7in)
	Depth 880mm (34.6in)
	Height 1280mm (50.4in)

Weight	
Operational weight (Dry)	150kg (331lb)
Shipping weight	217kg (479lb)

Chemicals	
Storage	Integral Chemical cupboard for 2 bottles
Size and Nature of Bottles	EDA+ or 3Ezyme Fluid: 10L (2.6US gal) plastic bottle
Quantity Used per Cycle	EDA+:360ml (12fl.oz US) or 3Ezyme:360ml (12fl.oz US)

Environmental conditions	
Use	Indoor, Altitude up to 2000m (6562ft)
Ambient Operating Temperature	5°C - 40°C (41°F - 104°F)
Humidity	Maximum relative humidity 80% for temperatures up to 31°C (87.8°F) decreasing linearly to 50% relative humidity at 40°C (104°F)
Noise	Max SPL 68dBA @ 1m from the front of the machine

Real Time Clock Battery	
Type	CR1220 (5012LC)
Typical Capacity	35 - 40 mAh
Standard Discharge Current	0.1 mA
Dimensions	12.5mm x 2.0mm

Range and Accuracy	
Water Temperature	Measurement range 2C° to 98C° (36°F to 208°F) Displayed and printed to the nearest °C or °F accuracy ±0.5°C or ±0.9°F Max water temperature: 95°C (limited by software and thermal trip)
Time	Displayed in minutes and seconds, accuracy ±0.5sec

Internal Data Storage	
Type	Micro SD FLASH Card
Typical Capacity	4GB (1 Million cycles)

5-2 Applied Standards

Standard	Description
BS EN ISO 15883-1:2009 +A1:2014	Washer-disinfectors. General requirements, terms and definitions and test
MDD 93/42/EEC	Medical Device Directive
BS EN ISO 15883-2:2009	Washer-disinfectors - Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.
BS EN 61010-1:2010	Safety requirements for electrical equipment for measurement, control, and laboratory use
BS EN 61010-2-040:2015	Particular requirements for sterilizers and washer-disinfectors used to treat medical materials
BS EN 60601-1-6:2010+A1:2015	Medical electrical equipment. General requirements for basic safety and essential performance
BS EN 60601-1:2006 +A12:2014	Medical electrical equipment. General requirements for basic safety and essential performance
BS EN 60601-1-2:2007	Medical electrical equipment. General requirements for basic safety and essential performance. Collateral Standard. Electromagnetic disturbances. Requirements and tests
BS EN 62366-1:2015	Medical devices. Application of usability engineering to medical devices
BS EN ISO 13485:2012	Medical devices - Quality management systems
BS EN ISO 14971:2012	Medical devices - Application of risk management to medical devices
PD IEC/TR 60878:2015	Graphical symbols for electrical equipment in medical practice
BS EN 1717:2000	Protection against pollution of potable water in water installations and general requirements of devices to prevent pollution by backflow
PD 5304:2014	Guidance on the safe use of machinery
EN 61326: 2013	Electrical equipment for measurement, control and laboratory use. EMC requirements. General requirements
UL 61010-1-2nd Edition	Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use
2003/10/EC	Minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (noise)
2009/104/EC	Minimum safety and health requirements for the use of work equipment by workers at work



6. Appendices

User Manual



EMC

6-1 EMC & Electromagnetic Compatibility Data

Instructions/Notes regarding the SI PCF and Electromagnetic compatibility (EMC) testing to EN60601-1-2:2007

The SI PCF has been tested regarding its ability to operate in an environment containing other electrical/electronic equipment (including other medical devices).

The purpose of this testing is to ensure that the SI PCF is not likely to adversely affect the normal operation of other such equipment and that other such equipment is not likely to adversely affect the normal operation of the SI PCF.

Despite the testing of the SI PCF that has been undertaken, normal operation can be affected by other electrical or electronic equipment. Portable and mobile RF communications equipment can affect medical electrical equipment.

As the SI PCF is medical equipment, special precautions are required regarding EMC.

It is important that the SI PCF is configured and installed/put into service, in accordance with the instructions/guidance provided herein and is used only in the configuration as supplied.

The SI PCF may be supplied with the following accessories: serial data cable (MED1017) and thermal printer (MED1014.1)

The SI PCF's data cable must be restricted to less than 3m in length and should not be extended by the user. If the SI PCF is used with adapted cables or cables other than those supplied, this may result in increased emissions or decreased immunity of the SI PCF, in relation to EMC performance.

If the SI PCF's is used with a printer other than the one supplied this may result in increased emissions or decreased immunity of the SI PCF, in relation to EMC performance.

It should be noted that the cables provided with the SI PCF should not be used on other equipment. To do so may result in increased emissions or decreased immunity of the other equipment in relation to EMC performance.

The SI PCF should not be used adjacent to or stacked with other equipment. If adjacent or stacked use with other equipment is necessary, the SI PCF and the other equipment should be observed / monitored to verify normal operation in the configuration in which it will be used.

For the purposes of EN60601-1-2, the SI PCF has an essential performance as follows:

Functions within the operating cycle should continue to operate as normal, and the product should complete its operating cycle correctly.

6-3 Electromagnetic Emissions

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The SI PCF is intended for use in the electromagnetic environment specified below. The customer or the user of the SI PCF should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The SI PCF uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The SI PCF is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not Applicable	

6-4 Electromagnetic Immunity

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The SI PCF is intended for use in the electromagnetic environment specified below. The customer or the user of the SI PCF should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input / output lines	± 2 kV for power supply lines Input / output line tests are not applicable.	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	$<5\% U_T$ ($>95\%$ dip in U_T) For 0.5 cycle $40\% U_T$ (60% dip in U_T) for 5 cycles $70\% U_T$ (30% dip in U_T) for 25 cycles $<5\% U_T$ ($>95\%$ dip in U_T) For 5 s	Not Applicable (Rated input current >16 A per phase) Not Applicable (Rated input current >16 A per phase) Not Applicable (Rated input current >16 A per phase) $<5\% U_T$ ($>95\%$ dip in U_T) For 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the SI PCF requires continued operation during power mains interruptions; it is recommended that the SI PCF be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) Magnetic field IEC 61000-4-8	3 A/m	3 A/m (50Hz only)	If incorrect operation occurs, it may be necessary to position the SI PCF further from sources of power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low.
Note: U_T is the A.C. mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The SI PCF is intended for use in the electromagnetic environment specified below. The customer or the user of the SI PCF should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the SI PCF, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance (d) $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Fields strengths from fixed RF transmitters, as determined by an electromagnetic site survey (see Note a) should be less than the compliance level in each frequency range (see Note b) Interference may occur in the vicinity of equipment marked with the following symbol: 
Note 1: At 80 MHz and 800 MHz, the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the SI PCF is used exceeds the applicable RF compliance level above, the SI PCF should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the SI PCF. b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

6-5 Separation Distances Between SI PCF and Mobile RF Equipment

Recommended separation distances between portable and mobile RF communications equipment and the SI PCF			
The SI PCF is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SI PCF can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SI PCF as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 KHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures objects and people.			

6-6 Warranty

To ensure continued efficiency and long operational life, your new SI PCF is covered by a one-year warranty/5,000 cycle warranty which is arranged and administered by Medisafe (UK) Ltd. Details of the warranty are explained in this section.

Subject to the following terms and conditions, Medisafe (UK) Ltd. warrants that any item of THE BASIC WARRANTY ITEMS of the unit (hereinafter called "new SI PCF") manufactured by Medisafe (UK) Ltd. shall be free from any defects in material and workmanship under normal use and maintenance.

Any item of THE BASIC WARRANTY ITEMS covered by the limited warranty will be repaired or replaced free of charge by Medisafe (UK) Ltd. or any distributor authorised by Medisafe (UK) Ltd. to act as their agent (hereinafter called "authorised Medisafe dealer or distributor").

The Basic Warranty Items

THE BASIC WARRANTY ITEMS are any items (except THE SPECIFIC EXCLUDED ITEMS) of this new SI PCF which are warranted by an authorised Medisafe dealer or distributor within 12 months or 5,000 cycles (whichever occurs first) of the WARRANTY START DATE when this new SI PCF is first installed by, or for you (the original purchaser) as set forth on the Memorandum of Registration.

THE BASIC WARRANTY ITEMS listed below are warranted within 12 months or 5,000 cycles (whichever occurs first) from the WARRANTY START DATE against defects in manufacture.

- Solenoid valves
- Electric motors and pumps
- Switches
- Electronic control circuits
- Water heating elements
- Ultrasonic transducers

The Specific Excluded Items

THE SPECIFIC EXCLUDED ITEMS are any items of this new SI PCF which are not included in THE BASIC WARRANTY ITEMS and are therefore not subject to the terms and conditions of the PRODUCT WARRANTY.

Expendable items, which will deteriorate and require replacement with normal use of the Washer (for example: lid seal, hose and luers, CPE ports, O-rings, various types of gaskets and hoses, LEDs (if fitted), and other expendable parts not specifically listed).

Fair wear and tear of any part, normal maintenance service items, and the parts and any material used in connection with the new SI PCF.

Normal deterioration or damage to plated parts, paint coat, and rubber parts, caused by daily wear and tear and exposure to atmosphere and environment.

Minor irregularities not affecting quality, performance or function of the new SI PCF parts thereof (e.g. slight noise or vibration) or which appear only under particular abnormal conditions.

Damage caused by insufficient or improper maintenance (e.g. negligence of the daily, weekly, and monthly periodic inspections and any servicing requirements as described and specified within this manual).

Damage caused by using a part or lubricants not approved by an authorised Medisafe dealer or distributor or being repaired or replaced by a person who is not an authorised Medisafe dealer or distributor.

Damage caused by accident, abuse, or negligence of the proper handling as set out in this Owner's Manual, misuse of the new SI PCF, use of the new SI PCF under unusual conditions, and modifications of or to the new SI PCF or any component/parts thereof not recommended or approved by an authorised Medisafe dealer or distributor.

Damage caused by external influences such as chemical spillage, accident, fire, and disasters due to human fault, negligence or Act of God.

Damage to the external casing, wash chamber, basket, or any part of the new SI PCF which may come into contact with the basket during the process of loading/ unloading the new SI PCF.

All charges incidental to breakdowns, such as loss of use of the new SI PCF, loss of time, inconvenience, telephone, transportation, loss or damage to personal property or loss of revenues, or other matter not specifically included.

Damage caused by incorrect installation of the new SI PCF, which could cause operational failure or impairment either immediately after such installation or at any time within the period of this PRODUCT WARRANTY.

Medisafe (UK) Ltd. reserves the right of final decision on all manufacturers' warranty claims.

Nothing herein affects the statutory rights of the consumer.

6-7 Service Record

Medisafe recommend that your SI PCF be serviced every 3 months in accordance with the schedule contained within the SI PCF Service Manual, which also contains the technical description of the machine. This record must be completed by the engineer conducting the service and should be made available in the event of a warranty claim or breakdown repair.

Note: No user serviceable parts inside. Service and repair should be referred to trained and qualified persons only - the product supplier (or Medisafe UK Ltd) to avoid personal injury, improper equipment performance, invalidation of the equipment warranty or other costly damage.

3 Month		
Serviced by/ Date		
Cycles since last service		
Next service due	Cycles	Date

6 Month		
Serviced by/ Date		
Cycles since last service		
Next service due	Cycles	Date

9 Month		
Serviced by/ Date		
Cycles since last service		
Next service due	Cycles	Date

12 Month		
Serviced by/ Date		
Cycles since last service		
Next service due	Cycles	Date

15 Month		
Serviced by/ Date		
Cycles since last service		
Next service due	Cycles	Date

18 Month		
Serviced by/ Date		
Cycles since last service		
Next service due	Cycles	Date

21 Month		
Serviced by/ Date		
Cycles since last service		
Next service due	Cycles	Date

24 Month		
Serviced by/ Date		
Cycles since last service		
Next service due	Cycles	Date

27 Month		
Serviced by/ Date		
Cycles since last service		
Next service due	Cycles	Date

30 Month		
Serviced by/ Date		
Cycles since last service		
Next service due	Cycles	Date

33 Month		
Serviced by/ Date		
Cycles since last service		
Next service due	Cycles	Date

36 Month		
Serviced by/ Date		
Cycles since last service		
Next service due	Cycles	Date

6-8 Operator PIN Number Codes

Operator #	Pin	Operator #	Pin	Operator #	Pin	Operator #	Pin
1	2040	21	4060	41	6080	61	8020
2	2181	22	4121	42	6141	62	8161
3	2262	23	4282	43	6222	63	8242
4	2363	24	4383	44	6323	64	8343
5	2484	25	4424	45	6444	65	8464
6	2545	26	4565	46	6585	66	8525
7	2626	27	4646	47	6666	67	8686
8	2727	28	4747	48	6776	68	8787
9	2848	29	4868	49	6888	69	8828
10	2989	30	4929	50	6949	70	8969
11	3070	31	5090	51	7030	71	9050
12	3171	32	5191	52	7131	72	9151
13	3292	33	5232	53	7252	73	9272
14	3353	34	5373	54	7393	74	9333
15	3434	35	5454	55	7474	75	9494
16	3535	36	5555	56	7575	76	9995
17	3656	37	5676	57	7696	77	9636
18	3797	38	5737	58	7757	78	9777
19	3878	39	5898	59	7838	79	9858
20	3979	40	5999	60	7939	80	9959

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6-9 Symbols Glossary

	Conformité Européenne: A conformity marking for certain products sold within the European Economic Area (EEA) since 1985. The CE marking is also found on products sold outside the EEA that are manufactured in, or designed to be sold in, the EEA. The 4-digit number below the CE mark is the identification number of the notified body involved in the conformity assessment procedure.
	UL (Underwriters Laboratories): An American worldwide safety consulting and certification company
	WEEE directive: Shows that a product can be recycled separately from other household waste under the WEEE directive
	Protective Earth symbol
	Standard Hazard Label (<i>used for Warnings and Hazards</i>)
	Standard Electrical Danger Label
	Mandatory Read - Read this manual before operating this machine