U.S. Department of Health & Human Services

Food and Drug Administration

FOIA RESPONSE

USER:	(ixg)
FOLDER:	K011071 - 150 pages (FOI:10002827)
COMPANY:	MAERSK MEDICAL A/S (MAERMEDIAS)
PRODUCT:	SET, ADMINISTRATION, INTRAVASCULAR (FPA)
SUMMARY:	Product: PARADIGM QUICK-SET INFUSION SET
DATE REQUESTED:	Nov 10, 2011
DATE PRINTED:	Nov 10, 2011
Note:	Releasable Version

MAERSK

K011071

JUN - 7 2001

Section C. 510(k) Summary

Submitter: Maersk Medical A/S Infusion Devices, Aaholmvej 1-3, Osted, DK-4000 Roskilde, Denmark

Maersk Contact: Mr. John M. Lindskog, General Manager, Maersk Medical A/S Infusion Devices
Telephone: + 45 48 16 70 00

U.S. Contact: Jennifer Lyons (818) 576-5189; Jennifer.Lyons@MiniMed.com

Name of Device: Paradigm™ Quick-set™ infusion set, models 396, 397, 398, 399

Predicate Device: Maersk Medical Quick-set™ infusion set (originally cleared under the name *Contour*)

Description of the New Device: The Paradigm Quick-set infusion sets are infusion administration sets, connecting to a MiniMed medication reservoir developed for use with a MiniMed Paradigm infusion pump and inserted in the subcutaneous tissue of a user.

The administration set attaches to the reservoir by means of a "tubing connector", and subcutaneously in the user through an indwelling catheter made of polytetrafluoroethylene (PTFE). The tubing is made of two layers: the inner layer is polyethylene; the outer is polyurethane. The 25 gauge indwelling catheter is introduced into the subcutaneous tissue by a removable 27 gauge introducer needle (cannula) made of 304 stainless steel. The needle, indwelling catheter, and tubing share a common hub.

Intended Use of the New Device: The Paradigm Quick-set infusion sets are intended for the subcutaneous infusion of medication, including insulin, from a MiniMed Paradigm infusion pump.

Comparison of the Technological Features of the New Device and Predicate Device: The modified device and the lawfully marketed predicate device differ only in the type of connector that attaches the infusion set to a reservoir. The modification does not affect the safety or effectiveness of the device.

Signed,

John M. Lindskog — 3/30-2001
John M. Lindskog — date
General Manager
Maersk Medical A/S

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 7 2001

Maersk Medical A/S
C/O Ms. Gerda Resch
Regulatory Affairs Manager
MiniMed Incorporated
18000 Devonshire Street
Northridge, California 91325

Re: K011071
Trade/Device Name: Paradigm Quick-Set Infusion Set
Regulation Number: 880.5440
Regulatory Class: II
Product Code: FPA
Dated: March 30, 2001
Received: April 9, 2001

Dear Ms. Lyons:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements

concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number:

Device Name: Paradigm Quick-set infusion set

Indications for Use: The Paradigm Quick-set infusion sets are indicated for the subcutaneous infusion of medication, including insulin, from a MiniMed Paradigm infusion pump.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ **or** **Over-the-Counter Use** _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control,
General Hospital Devices
510(k) Number K011071

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 7 2001

Maersk Medical A/S
C/O Ms. Gerda Resch
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Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number:

Device Name: Paradigm Quick-set infusion set

Indications for Use: The Paradigm Quick-set infusion sets are indicated for the subcutaneous infusion of medication, including insulin, from a MiniMed Paradigm infusion pump.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ **or** **Over-the-Counter Use** _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control,
General Hospital Devices
510(k) Number K011071

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: 6/7/01

From: Reviewer(s) - Name(s) Irene Naveau

Subject: 510(k) Number K011071

To: The Record - It is my recommendation that the subject 510(k) Notification:

- ☐ Refused to accept.
- ☐ Requires additional information (other than refuse to accept).
- ☒ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
  - De Novo Classification Candidate? ☐ YES ☐ NO
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Postmarket Surveillance?	☐ YES	☒ NO
Is this device subject to the Tracking Regulation?	☐ YES	☒ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☒ NO
Is this a prescription device?	☒ YES	☐ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☒ NO
Special 510(k)?	☐ YES	☒ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☐ YES	☒ NO

This 510(k) contains:

Truthful and Accurate Statement ☐ Requested ☒ Enclosed
(required for originals received 3-14-95 and after)

- ☒ A 510(k) summary OR ☐ A 510(k) statement
- ☐ The required certification and summary for class III devices
- ☒ The indication for use form (required for originals received 1-1-96 and after)
- Material of Biological Origin ☐ YES ☐ NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

Predicate Product Code with class: 80/FPA/II/880.5440

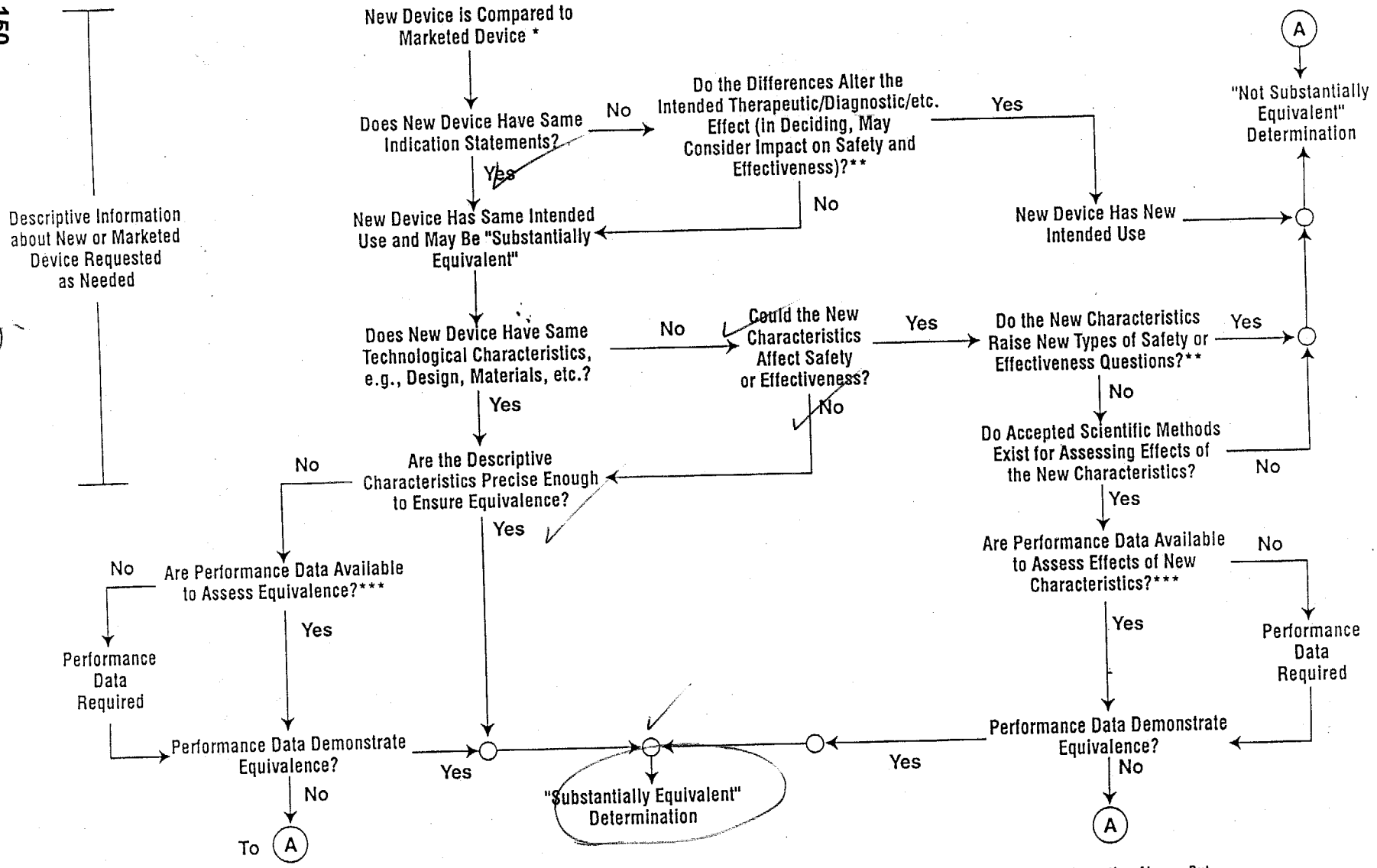
Additional Product Code(s) with panel (optional):

Review: Patricia Cucente (Branch Chief) HDB (Branch Code) 6/7/01 (Date)

Final Review: (Division Director) (Date) 6/7/01

Revised:8/17//99

510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



* 510(k) Submissions Compare New Devices to Marketed Devices. FDA Requests Additional Information if the Relationship Between Marketed and "Predicate" (Pre-Amendments or Reclassified Post-Amendments) Devices is Unclear.

** This Decision is Normally Based on Descriptive Information Alone, But Limited Testing Information is Sometimes Required.

*** Data May Be in the 510(k), Other 510(k)s, The Center's Classification Files, or the Literature.

SE MEMO TO THE RECORD

510(k) REVIEW

K011071

DATE: June 7, 2001
FROM: Irene Naveau

OFFICE: HFZ-480
DIVISION: DDIG/GHDB

COMPANY NAME: Maersk Medical A/S
DEVICE NAME: Paradigm™ Quick-set™ Infusion Set Models MMT-396,397,398,399

NARRATIVE DEVICE DESCRIPTION

1. SUMMARY DESCRIPTION OF THE DEVICE UNDER REVIEW:

The Paradigm™ Quick-set™ Infusion Set is (b)(4),(b)(5)

(b)(4),(b)(5)

(b)(4),(b)(5)

Refer to Appendix 8 for chemical formulation of all materials for this device.

2. INTENDED USE: For the subcutaneous infusion of medication, including insulin, from a MiniMed Paradigm infusion pump.

3. DEVICE DESCRIPTION:

A. Life-supporting or life-sustaining: No
B. Implant (short-term or long-term): No

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C. Is the device sterile? Yes

Method	(b)(4),(b)(5)
Validation	
SAL	10^{-6}
Dosage	(b)(4),(b)(5)
Pyrogenicity	

Packaging: (b)(4),(b)(5)
(b)(4),(b)(5)

D. Is the device for single use? Yes
E. Is the device for prescription use? Yes
F. Is the device for home use or portable? Yes

G. Does the device contain drug or biological product as a component? No
H. Is this device a kit? No
I. Software driven: No
J. Electrically Operated: No
K. Applicable standards to which conformance has been demonstrated (e.g., IEC, ANSI, ASTM, etc.): N/A

L. Device(s) to which equivalence is claimed, manufacturer, and 510(k) number or preamendment status: Contour™ (Quick-set) Subcutaneous Infusion Sets, Maersk Medical A/S, K991759.

M. Submission provides comparative specifications a Yes
performance data b Yes
biocompatibility testing c No
The sponsor states that the administration set does meets the specifications of the ISO 10993 standard.

N. Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

(b)(4),(b)(5)

(b)(4),(b)(5)

The labeling for this device is adequate. It contains pertinent information specific to the device, and detailed instructions for use with pictorials.

Based on the information provided in this 510(k) submission, I believe that this device is substantially equivalent to the predicate device (section L). No new issues of safety and effectiveness exist for this device.

M. Does the submission include a summary of safety and effectiveness information upon which an equivalence determination is based? Yes

N. RECOMMENDATION:

I believe that this device is equivalent to: 80 FPA

Classification should be based on: Intravascular Administration Set

880.5440 Class: II

Irene Naveau 6/7/01

Irene Naveau

PC
6/7/01

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"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K011071

Reviewer: Irene Naveau

Division/Branch: DDIGD/GHDB

Device Name: Paradigm™ Quick-set™ Infusion Set Models MMT 396 397 398 399

Product To Which Compared (510(K) Number If Known): Contour™ (Quick-set) Subcutaneous Infusion Sets, Maersk Medical A/S, K991759.

	YES	NO	
1. Is Product A Device	X		If **NO** = Stop
2. Is Device Subject To 510(k)?	X		If **NO** = Stop
3. Same Indication Statement?	X		If **YES** = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NE**
5. Same Technological Characteristics?		x	If **YES** = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?		X	If **YES** = Go To 8
7. Descriptive Characteristics Precise Enough?	X		If **NO** = Go To 10 If **YES** = Stop **SE**
8. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NE**
9. Accepted Scientific Methods Exist?			If **NO** = Stop **NE**
10. Performance Data Available?			If **NO** = Request Data
11. Data Demonstrate Equivalence?			Final Decision: SE

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

1. Intended Use: For the subcutaneous infusion of medication, including insulin, from a MiniMed Paradigm infusion pump.

2. Device Description: Refer to SE Memo dated June 7, 2001.

5. Describe the new technological characteristics: This device has a proprietary tubing connector that replaces the proximal luer connector of the predicate device. The proprietary tubing connector is compatible with the MiniMed Paradigm infusion pump.

6. Explain how new characteristics could or could not affect safety or effectiveness: The new characteristic does not affect the intended use of this device or its basic characteristics. The safety and effectiveness of this device is not affected by the new characteristic.

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K011071

MiniMed®
Advancing solutions in diabetes

May 31, 2001

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850
Attn: Irene Naveau

Re: Contact Change for Paradigm Quick-set Infusion Set – K011071

Dear Ms. Naveau:

As my last day at MiniMed will be Friday, June 1, please forward all correspondence for Premarket Notification K011071 to Gerda Resch, Regulatory Affairs Manager. Her mailing address is 18000 Devonshire St., Northridge, CA 91325. She may be reached at (818) 576-4198.

Sincerely,

Jennifer Lyons
Regulatory Affairs Specialist
MiniMed Inc.

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SIS 6

K011071 / A1

MAERSK

April 25, 2001

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850
Attn: Irene Naveau

Re: 510(k) Notification for the Paradigm Quick-set (K011071); Additional Information, as requested

Dear Ms. Naveau:

Following is the information you requested for the Paradigm Quick-set infusion sets.

- The risk analysis for the Paradigm Quick-set with conclusions is provided in Attachment 1. "Marilyn" was used as a development name for "Quick-set."
- A biocompatibility declaration of conformity is provided in Attachment 2.
- The packaging material for the infusion set is composed of a clear "blister" portion and a top-stock / paper lid. The clear portion is made of rigid polyester laminated with polyethylene (APET/PE, 450/50). The top-stock / paper lid is a medical grade paper. Both materials are recommended for ethylene oxide sterilization. The data sheets for both materials are provided in Attachment 3.

If you have additional question, please contact Jennifer Lyons, who may be reached, via MiniMed Inc. at (818) 576-5189. Her mailing address is Regulatory Affairs, MiniMed Inc., 18000 Devonshire St, Northridge, CA 91325.

Sincerely,

John M. Lindskog
General Manager
Maersk Medical A/S
Infusion Devices

cc: Jennifer Lyons; Regulatory Affairs, MiniMed Inc.

CONFIDENTIAL

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SK55

MAERSK

TABLE OF CONTENTS

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Attachment 1. Risk Analysis

(b)(4),Testing Data

(b)(4),Testing Data

(b)(4),Testing Data

(b)(4),Testing Data

(b)(4),Testing Data

MAERSK

Attachment 2. Biocompatibility Certification

MAERSK

BIOCOMPATIBILITY CERTIFICATION

As a responsible official of Maersk Medical A/S, I hereby certify that the Paradigm Quick-set infusion set will conform to FDA recognized standard ISO 10993-1 before any device is delivered to the marketplace.

Signed,

John M. Lindskog
General Manager
Maersk Medical A/S
Infusion Devices

date 4/25/2001

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MAERSK

Attachment 3 Material specifications packaging material

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(b)(4),Technical Information-CCI

(b)(4),Technical Information-CCI

(b)(4),Technical Information-CCI

DATE: April 18, 2001

MEMORANDUM OF TELEPHONE CONVERSATION

Between: Irene Naveau, Nurse Consultant
DDIG/GHDB, HFZ-480

And: Ms. Jennifer Lyons
Contact for Maersk Medical A/S
(818) 362-5958

Re: K011071, Paradigm Quick-Set Infusion Set (models 396-397-398-399)

(b)(4),(b)(5)

Irene Naveau 4/18/01

Irene Naveau

Screening Checklist
For all Premarket Notification 510(k) Submissions

3-30-01

Device Name: Paradigm Quick-Set Module MMT 396 | K011071

Submitter (Company): Maersk Medical A/S

Items which should be included *(circle missing & needed information)*	SPECIAL YES	SPECIAL NO	ABBREVIATED YES	ABBREVIATED NO	TRADITIONAL YES	TRADITIONAL NO	✓ IF ITEM IS NEEDED AND IS MISSING
1. Cover Letter clearly identifies Submission as:							
a) "Special 510(k): Device Modification"	GO TO # 2,3		GO TO # 2,4,5		GO TO #2, 5	✓	
b) "Abbreviated 510(k)"							
c) Traditional 510(k)							

2. GENERAL INFORMATION: REQUIRED IN ALL 510(K) SUBMISSIONS	NA SPECIALS YES	NA SPECIALS NO	YES ABBREVIATED YES	YES ABBREVIATED NO	NO TRADITIONAL YES	NO TRADITIONAL NO	✓ IF ITEM IS NEEDED AND IS MISSING
Financial Certification or Disclosure Statement for 510(k)s with a Clinical Study 807.87(i) including forms 3454 and/or 3455							
a) trade name, classification name, establishment registration number, device class					✓		
b) OR a statement that the device is not yet classified	FDA-may be a classification request; see coordinator						
c) identification of legally marketed equivalent device	NA				✓		
d) compliance with Section 514 - performance standards	NA				✓		
e) address of manufacturer					✓		
f) Truthful and Accurate Statement					✓		
g) Indications for Use enclosure					✓		
h) SMDA Summary or Statement *(FOR ALL DEVICE CLASSES)*					✓		
i) Class III Certification & Summary *(FOR ALL CLASS III DEVICES)*							
j) Description of device (or modification) including diagrams, engineering drawings, photographs, service manuals					✓		
k) Proposed Labeling:					✓		
i) package labeling (user info)					✓		
ii) statement of intended use					✓		
iii) advertisements or promotional materials					✓		
i) MRI compatibility (if claimed)							
l) Comparison Information (similarities and differences) to named legally marketed equivalent device (table preferred) should include:					✓		
i) Labeling					✓		
ii) intended use							
iii) physical characteristics							
iv) anatomical sites of use							
v) performance (bench, animal, clinical) testing	NA						
vi) safety characteristics	NA						
m) If kit, kit certification							

3. "SPECIALS" - ONLY FOR MODIFICATIONS TO MANUFACTURER'S OWN CLASS II , III OR RESERVED CLASS I DEVICE				
a) Name & 510(k) number of legally marketed (unmodified) predicate device				N/A
b) ***STATEMENT - INTENDED USE AND INDICATIONS FOR USE OF MODIFIED DEVICE AS DESCRIBED IN ITS***			* If no - STOP not a special	

	LABELING HAVE NOT CHANGED*			
c)	***STATEMENT - FUNDAMENTAL SCIENTIFIC TECHNOLOGY OF THE MODIFIED DEVICE HAS NOT CHANGED****		* if no - STOP not a special	
d)	Design Control Activities Summary			
	i) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis			
	ii) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied			
	iii) A declaration of conformity with design controls. The declaration of conformity should include:			
	1) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met			
	2) A statement signed by the individual responsible, that manufacturing facility is in conformance with design control procedure Requirements as specified in 21 CFR 820.30 and the records are available for review.			

	SPECIALS		ABBREVIATED		TRADITIONAL		✓ IF ITEM IS NEEDED AND IS MISSING
	YES	NO	YES	NO	YES	NO	
4. ABBREVIATED 510(K): SPECIAL CONTROLS/CONFORMANCE TO RECOGNIZED STANDARDS - PLEASE FILL OUT THE STANDARDS ABBREVIATED FORM ON THE H DRIVE							
a) For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type							
b) If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.							
c) For a submission, which relies on a recognized standard, a declaration of conformity to the standard. The declaration should include the following:							
i) An identification of the applicable recognized consensus standards that were met							
ii) A specification, for each consensus standard, that all requirements were met, except for inapplicable requirements or deviations noted below							
iii) An identification, for each consensus standard, of							

any way(s) in which the standard may have been adapted for application to the device under review, e.g., an identification of an alternative series of tests that were performed							
iv) An identification, for each consensus standard, of any requirements that were not applicable to the device							
v) A specification of any deviations from each applicable standard that were applied							
vi) A specification of the differences that may exist, if any, between the tested device and the device to be marketed and a justification of the test results in these areas of difference							
vii) Name/address of test laboratory/certification body involved in determining the conformance of the device with applicable consensus standards and a reference to any accreditations for those organizations							
d) Data/information to address issues not covered by guidance documents, special controls, and/or recognized standards							

5. Additional Considerations: (may be covered by Design Controls)							
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:							
i) component & material							
ii) identify patient-contacting materials							
iii) biocompatibility of final sterilized product							
b) Sterilization and expiration dating information:							
i) sterilization method							
ii) SAL							
iii) packaging							
iv) specify pyrogen free							
v) ETO residues							
vi) radiation dose							
c) Software validation & verification:							
i) hazard analysis							
ii) level of concern							
iii) development documentation							
iv) certification							

Items shaded under "NO" are necessary for that type of submission. Circled items and items with check in the "Needed & Missing" column must be submitted before acceptance of the document.

Passed Screening ✓ **Yes** ____ **No** **Reviewer:** Irene Naveau

Concurrence by Review Branch: ____

Date: APR 11 2001

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Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		✓
2. Did we grant expedited review?		✓
3. Have you verified that the Document is labeled Class III for GMP purposes?		✓
4. If, not, has POS been notified?		✓
5. Is the product a device?	✓	✓
6. Is the device exempt from 510(k) by regulation or policy?		✓
7. Is the device subject to review by CDRH?		
8. Are you aware that this device has been the subject of a previous NSE decision?		✓
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		✓
10. Are you aware of the submitter being the subject of an integrity investigation?		✓
11. If, yes, consult the ODE Integrity Officer.		
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.		✓

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REVISED:3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K_____

Reviewer:_____

Division/Branch:_____

Device Name:_____

Product To Which Compared (510(K) Number If Known):_____

	YES	NO	
1. Is Product A Device			If **NO** = Stop
2. Is Device Subject To 510(k)?			If **NO** = Stop
3. Same Indication Statement?			If **YES** = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NE**
5. Same Technological Characteristics?			If **YES** = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 8
7. Descriptive Characteristics Precise Enough?			If **NO** = Go To 10 If **YES** = Stop **SE**
8. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NE**
9. Accepted Scientific Methods Exist?			If **NO** = Stop **NE**
10. Performance Data Available?			If **NO** = Request Data
11. Data Demonstrate Equivalence?			Final Decision:

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

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1. Intended Use:

2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device over-the-counter or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:

2. Explain why not subject to 510(k):

3. How does the new indication differ from the predicate device's indication:

4. Explain why there is or is not a new effect or safety or effectiveness issue:

5. Describe the new technological characteristics:

6. Explain how new characteristics could or could not affect safety or effectiveness:

7. Explain how descriptive characteristics are not precise enough:

8. Explain new types of safety or effectiveness questions raised or why the questions are not new:

9. Explain why existing scientific methods can not be used:

10. Explain what performance data is needed:

11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

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Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

April 10, 2001

MAERSK MEDICAL A/S
C/O MINIMED INC.
18000 DEVONSHIRE STREET
NORTHRIDGE, CA
ATTN: JENNIFER LYONS

510(k) Number: K011071
Received: 09-APR-2001
Product: PARADIGM QUICK-SET
MODELS
MMT-396,397,398,399

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

On January 1, 1996, FDA began requiring that all 510(k) submitters provide on a separate page and clearly marked "Indication For Use" the indication for use of their device. If you have not included this information on a separate page in your submission, please complete the attached and amend your 510(k) as soon as possible. Also if you have not included your 510(k) Summary or 510(k) Statement, or your Truthful and Accurate Statement, please do so as soon as possible. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522(a)(1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers Assistance (DSMA) at the telephone or web site below for more information.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official. Any telefaxed material must be followed by a hard copy to the Document Mail Center (HFZ-401).

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMA. If you have other procedural or policy questions, or want information on how to check on the status of your submission (after 90 days from the receipt date), please contact DSMA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsmamain.html or me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Staff
Office of Device Evaluation

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MAERSK

K011071

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

March 30, 2001

Re: **510(k) Notification** for the Maersk Medical A/S Paradigm™ Quick-set™ infusion set, models 396, 397, 398, 399

Dear Sir or Madam:

Pursuant to the requirements of Section 510(k) of the Federal Food, Drug and Cosmetic Act, notification is made of the intention of Maersk Medical A/S to introduce to the marketplace a modified version of the Maersk Medical Quick-set Infusion Set Models 82-060-2626; 82-060-2629; 82-110-2626; 82-110-2629, cleared through premarket notification K991759 under the name *Contour,* which will be named the Paradigm Quick-set infusion set, models 396, 397, 398, 399. These sets are to be marketed exclusively by MiniMed Inc.

A detailed description of the new device is enclosed, as are prototype labels and labeling. Labels and labeling of the predicate device are also enclosed. A sample of the Paradigm Quick-set infusion set is included in an accompanying package.

In response to requirements of the SMDA of 1990, included is a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

This 510(k) Notification is formatted as outlined in the guidance document "Premarket Notification 510(k): Regulatory Requirements for Medical Devices, 95-4158." Additionally, an annotated copy of the checklist from the March 1995 document "Center for Devices and Radiological Health's Premarket Notification for 510(k) Refuse to Accept Checklist" is provided.

Should you require additional information, please do not hesitate to contact the undersigned.

Our U.S. contact for this submission is Jennifer Lyons, who may be reached, via MiniMed Inc. at (818) 576-5189. An e-mail message may be sent to Ms. Lyons at Jennifer.Lyons@MiniMed.com. Her mailing address is Regulatory Affairs, MiniMed Inc., 18000 Devonshire Street, Northridge, CA 91325.

Sincerely,

John M. Lindskog
General Manager
Maersk Medical A/S
Infusion Devices

Contents: 510(k) Notification - Original and two copies

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CONFIDENTIAL

CDRH SUBMISSION COVER SHEET

Date of Submission:	FDA Document Number:
March X, 2001	

Section A — Type of Submission

PMA	PMA Supplement	PDP	510(k)	Meeting
Original Submission Modular Submission Amendment Report Report Amendment	Regular Special Panel Track 30-day Supplement 30-day Notice 135-day Supplement Real-time Review Amendment to PMA Supplement	Presubmission Summary Original PDP Notice of intent to start clinical trials Intention to submit Notice of Completion Notice of Completion Amendment to PDP Report	Original Submission: Traditional ✓ Special Abbreviated Additional Information Traditional Special Abbreviated	Pre-IDE Meeting Pre-PMA Meeting Pre-PDP Meeting 180-day Meeting Other (specify):

IDE	Humanitarian Device Exemption	Class II Exemption	Evaluation of Automatic Class III Designation	Other Submission
Original Submission Amendment Supplement	Original Submission Amendment Supplement Report	Original Submission Additional Information	Original Submission Additional Information	Describe Submission:

Section B — Applicant or Sponsor

Company/Institution Name: **Maersk Medical A/S**		Establishment Registration Number: **8021545**
Division Name (If Applicable): **Infusion Devices**		Phone Number (Include Area Code): **45 48 16 70 00**
Street Address: **Aaholmvej 1-3**		Fax Number (Include Area Code):
City: **Osted**	State/Province: **DK-4000 Roskilde**	Country: **Denmark**
Contact Name: **John M. Lindskog**		
Contact Title: **General Manager, Infusion Devices**		Contact E-Mail Address:

Section C — Submission Correspondent (if different from above)

Company/Institution Name: **MiniMed Inc.**		Establishment Registration Number:
Division Name (If Applicable):		Phone Number (Include Area Code): **(818) 362-5958**
Street Address: **18000 Devonshire St.**		Fax Number (Include Area Code): **(818) 576-6273**
City: **Northridge**	State/Province: **California**	Country: **USA**
Contact Name: **Jennifer Lyons**		
Contact Title: **Regulatory Affairs Specialist**		Contact E-Mail Address: **Jennifer.Lyons@MiniMed.com**

Section D1 Reason for Submission --- PMA, PDP, or HDE

New Device
Withdrawal
Additional or expanded indications
Licensing agreement

Process change:
- Manufacturing
- Sterilization
- Packaging
- Other (specify below)

Response to FDA Correspondence
- Request for applicant hold
- Request for removal of applicant hold
- Request for extension
- Request to remove or add manufacturing site

Other reason (specify):

Change in design, component, or specification:
- Software
- Color Additive
- Material
- Specifications
- Other (specify other)

Labeling change:
- Indications
- Instructions
- Performance Characteristics
- Shelf life
- Trade name
- Other (specify below)

Location change:
- Manufacturer
- Sterilizer
- Packager
- Distributor

Report submission:
- Annual or periodic
- Post-approval study
- Adverse reaction
- Device defect
- Amendment

Change in ownership
Change in correspondent

Section D2 Reason for Submission ----IDE

New Device
Addition of institution
Expansion/extension of study
IRB certification
Request hearing
Request waiver
Termination of study
Withdrawal of application
Unanticipated adverse effect
Notification of emergency use
Compassionate use request
Treatment IDE
Continuing availability request

Other reason (specify):

Change in:
- Correspondent
- Design
- Informed consent
- Manufacturer
- Manufacturing process
- Protocol - feasibility
- Protocol - other
- Sponsor

Report submission:
- Current investigator
- Annual progress
- Site waiver limit reached
- Final

Response to FDA letter concerning:
- Conditional approval
- Deemed approved
- Deficient final report
- Deficient progress report
- Deficient investigator report
- Disapproval
- Request extension of time to respond to FDA
- Request meeting

Section D3 Reason for Submission --- 510(k)

New Device
Additional or expanded indications
Other reason (specify):

Change in technology
Change in design

Change in materials
Change in manufacturing process

Section E — Additional Information on 510(k) Submissions

Product codes of devices to which substantial equivalence is claimed			Summary of statement concerning, safety and effectiveness data: 510(k) summary attached 510(k) statement
1 **80FPA; 80FPK**	2	3	4
5	6	7	8

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 **K991759**	1 **Quick-set (submitted as Contour)**	1 **Maersk Medical**
2	2	2
3	3	3
4	4	4
5	5	5
6	6	6

Section F — Product Information – Applicable to All Applications

Common or usual name or classification name: **Subcutaneous Infusion Administration Set**

Trade or Proprietary or Model Name	Model Number
1 **Paradigm Quick-set**	1 **Models MMT-396, 397, 398, 399**
2	2
3	3
4	4
5	5

FDA document numbers of all prior related submissions (regardless of outcome):

1	2	3	4	5	6
7	8	9	10	11	12

Data included in submission: Laboratory testing Animal trials Human trials

Section G — Product Classification – Applicable to All Applications

Product Code: **80FPA; 80FPK**	C.F.R. Section: **880.5440**	Device Class: Class I Class II ✗ Class III Unclassified

Classification Panel: **General Hospital and Personal Use Panel: (80)**

Indications (from labeling): **The Paradigm Quick-set infusion sets are indicated for the subcutaneous infusion of medication, including insulin, from a MiniMed Paradigm infusion pump.**

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number:

Section H	Manufacturing/Packaging/Sterilization Sites Relating to a Submission	
Original Add Delete	FDA Establishment Registration Number:	Manufacturer Contract Sterilizer Contract Manufacturer Repackager/Relabeler
Company/Institution Name: (b)(4)		Establishment Registration Number: (b)(4)
Division Name (If Applicable):		Phone Number (Include Area Code):
Street Address: (b)(4)		Fax Number (Include Area Code):
City: (b)(4)	State/Province: (b)(4)	Country: (b)(4)
Contact Name:		
Contact Title:		Contact E-Mail Address:
Original Add Delete	FDA Established Registration Number:	Manufacturer Sterilizer Contract Manufacturer Repackager/Relabeler
Company/Institution Name: (b)(4)		Establishment Registration Number:
Division Name (If Applicable):		Phone Number (Include Area Code): (b)(4)
Street Address: (b)(4)		Fax Number (Include Area Code): ()
City: (b)(4)	State/Province: (b)(4)	Country: (b)(4)
Contact Name:		
Contact Title:		Contact E-Mail Address:
Original Add Delete	FDA Established Registration Number:	Manufacturer Contract Sterilizer Contract Manufacturer Repackager/Relabeler
Company/Institution Name:		Establishment Registration Number:
Division Name (If Applicable):		Phone Number (Include Area Code): ( )
Street Address:		Fax Number (Include Area Code): ( )
City:	State/Province:	Country:
Contact Name:		
Contact Title:		Contact E-Mail Address:

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TOPIC **PAGE**

JP

TABLE OF CONTENTS - Continued

TOPIC **PAGE**

TABLE OF CONTENTS - Continued

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Section A. Annotated Checklist for Acceptance

Question		Yes	No	N/A	Page
I. Critical Elements					
A. Is the product a device?		_X_	___	___	
B. Is the device exempt from 510(k) by regulation or policy?		___	_X_	___	
C. Is the device subject to review by CDRH?		_X_	___	___	
D. Are you aware of this device being the subject of a previous NSE decision?	___	_X_	___		
E. Are you aware of the submitter being the subject of an integrity investigation?	___	_X_	___		
F. Does the submission contain the information required?					
Device trade name		_X_	___	___	___
Device common name		_X_	___	___	___
Establishment registration number		_X_	___	___	___
Device classification		_X_	___	___	___
Classification panel		_X_	___	___	___
Section 514 action		_X_	___	___	___
Proposed labels, labeling		_X_	___	___	___
510(k) Summary/Statement		_X_	___	___	___
Photographs/drawings of the device		_X_	___	___	___
Engineering drawings		_X_	___	___	___
Labeling of predicate		_X_	___	___	___
Statement of similarities and/or differences		_X_	___	___	___

Checklist for Acceptance - Continued

Question	Yes	No	N/A	Page
Data re: modified device	_X_	___	___	___
Truthful and Accurate Statement	_X_	___	___	___
Indications for Use statement	_X_	___	___	___
II. Additional necessary information				
A. Submitter's name/address	_X_	___	___	___
B. Contact person information	_X_	___	___	___
C. Representative/consultant	_X_	___	___	___
D. Table of Contents	_X_	___	___	___
E. Address of Mfg. facility	_X_	___	___	___
III. Additional information				
A. Comparison table	_X_	___	___	___
B. Voluntary standards action	_X_	___	___	___
C. Performance Data	_X_	___	___	___
D. Sterilization information	_X_	___	___	___
E. Software information	___	___	_X_	___
F. Hardware information	___	___	_X_	___
G. Kit certification statement	___	___	_X_	___
H. Guidance document issues	_X_	___	___	___

UM

Section B. 510(k) Summary Checklist

Requirement	Yes	No	N/A
1. Separate section of the submission	_X_	___	___
2. Submitter information; date	_X_	___	___
3. Identification of new device	_X_	___	___
4. Identification of predicate device	_X_	___	___
5. Description of new device	_X_	___	___
6. Intended use of new device	_X_	___	___
7. Summary of comparison of technological characteristics	_X_	___	___
8. Discussion of nonclinical data, if any	___	___	_X_
9. Conclusions from clinical/nonclinical studies, if any	___	___	_X_
10. Contents of summary:			
a. All information is contained in the submission	_X_	___	___
b. No unsubstantiated labeling claims	_X_	___	___
c. No raw data; only summaries	_X_	___	___
d. No trade secret/confidential information	_X_	___	___
e. No patient identification information	_X_	___	___

MAERSK

Section C. 510(k) Summary

Submitter: Maersk Medical A/S Infusion Devices, Aaholmvej 1-3, Osted, DK-4000 Roskilde, Denmark

Maersk Contact: Mr. John M. Lindskog, General Manager, Maersk Medical A/S Infusion Devices
Telephone: + 45 48 16 70 00

U.S. Contact: Jennifer Lyons (818) 576-5189; Jennifer.Lyons@MiniMed.com

Name of Device: Paradigm™ Quick-set™ infusion set, models 396, 397, 398, 399

Predicate Device: Maersk Medical Quick-set™ infusion set (originally cleared under the name *Contour*)

Description of the New Device: The Paradigm Quick-set infusion sets are infusion administration sets, connecting to a MiniMed medication reservoir developed for use with a MiniMed Paradigm infusion pump and inserted in the subcutaneous tissue of a user.

The administration set attaches to the reservoir by means of a "tubing connector", and subcutaneously in the user through an indwelling catheter made of polytetrafluoroethylene (PTFE). The tubing is made of two layers: the inner layer is polyethylene; the outer is polyurethane. The 25 gauge indwelling catheter is introduced into the subcutaneous tissue by a removable 27 gauge introducer needle (cannula) made of 304 stainless steel. The needle, indwelling catheter, and tubing share a common hub.

Intended Use of the New Device: The Paradigm Quick-set infusion sets are intended for the subcutaneous infusion of medication, including insulin, from a MiniMed Paradigm infusion pump.

Comparison of the Technological Features of the New Device and Predicate Device: The modified device and the lawfully marketed predicate device differ only in the type of connector that attaches the infusion set to a reservoir. The modification does not affect the safety or effectiveness of the device.

Signed,

John M. Lindskog 3/30-2001
John M. Lindskog date
General Manager
Maersk Medical A/S

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Section D. Certifications

Truthful and Accurate Statement

2. Indications for Use Statement

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PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT

I hereby certify, as a responsible representative of Maersk Medical A/S, that I believe to the best of my knowledge and understanding, that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.

Signed,

John M. Lindskog 3/30-2001
John M. Lindskog date
General Manager
Maersk Medical A/S

Premarket Notification [510(k)] Number

MAERSK

INDICATIONS FOR USE

510(k) Number:

Device Name: Paradigm Quick-set infusion set

Indications for Use: The Paradigm Quick-set infusion sets are indicated for the subcutaneous infusion of medication, including insulin, from a MiniMed Paradigm infusion pump.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ **or** **Over-the-Counter Use** _____
(Per 21 CFR 801.109)

MAERSK

Section E. Submitter Information

1. Applicant

Maersk Medical A/S
Infusion Devices
Aaholmvej 1-3, Osted
DK-4000 Roskilde, Denmark

2. Contact Person

Jennifer Lyons
Regulatory Affairs Specialist
MiniMed Inc.
(818) 576-5189
FAX: (818) 576-6273
Internet: Jennifer.Lyons@MiniMed.com

3. Representative/Consultant

Jennifer Lyons
Regulatory Affairs Specialist
MiniMed Inc.
(818) 576-5189
FAX: (818) 576-6273
Internet: Jennifer.Lyons@MiniMed.com

4. Establishment Registration Number

8021545

5. Address of Manufacturing Site

(b)(4)

MAERSK

6. Purpose of the Submission

This submission describes a device, which is a modification of the Quick-set infusion set, cleared through premarket notification K991759 under the name Maersk Medical Contour™, to be named the Paradigm Quick-set infusion set. The existing infusion set will continue to be marketed by MiniMed Inc.

(b)(4)

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Section F. Description of the New Device

1. Device Trade or Proprietary Name

Paradigm Quick-set infusion set

2. Device Common and Classification Name(s)

Common Name:	Subcutaneous Infusion Administration Set
Classification Name:	Intravascular Administration Set
	Fluid Delivery Tubing

3. Device Classification Information

Class:	II
Panel:	80
Product Code:	80FPA; 80FPK
Cite:	21 CFR 880.5440

4. Description of the New Device

a. Type of device: The Paradigm Quick-set infusion sets are infusion administration sets, connecting to a MiniMed Paradigm medication reservoir proximally. The infusion set is inserted in the subcutaneous tissue of a user.

(b)(4)

SV

(b)(4)

The combination of two tubing lengths and two catheter lengths results in four models of the device:

Model Number	Tubing Length	Catheter Length
(b)(4)	23 in.	6 mm
	23 in.	9 mm
	43 in.	6 mm
	43 in.	9 mm

b. Statement of intended use: The Paradigm Quick-set infusion set is intended for the subcutaneous infusion of medication, including insulin, from a MiniMed Paradigm infusion pump.

c. Use with other devices: The new infusion set will be marketed exclusively by MiniMed Inc. for use with the following MiniMed products:

Model Number	"K" Number	Device Type
511	K001829	Paradigm Insulin Infusion Pump
326	K001828	Paradigm User-filled Reservoir
395	K992300	Quick-serter™ Insertion device

Other infusion pumps and reservoirs are in development by MiniMed Inc. and may be designed for use with the Paradigm Quick-set infusion set.

d. Physical specifications

i. **Components and materials:** Following is a list of the principal components of the Paradigm Quick-set infusion set:

Part Description	Material
Tubing Connector	(b)(4)
Tubing Connector needle	(b)(4)
Tubing Connector vent	
Tubing	
Inside	
Outside	
Introducer needle hub	
Introducer needle	
Connector	
Lid	
Septum	
Catheter bushing	
Catheter	
Sealing ring	
Base piece	
Gasket	
Adhesive tape	
Introducer needle guard	
Dummy connector	

A matrix showing the material brand and formulation numbers is presented in Appendix 8.

ii. **Other materials:** The materials listed below are also used in the fabrication of the Paradigm Quick-set infusion set:

™ Quick-serter is a Trademark of MiniMed Inc.

Material	Comments
Silicone oil	(b)(4)
UV Adhesive	

iii. Nominal dimensions:

ID of tubing:	(b)(4)
OD of tubing:	
Tubing length:	23 in.; 43 in.
Number of lumens:	One
Shape of lumen:	Round
Tip configuration:	PTFE catheter over needle
ID of catheter:	(b)(4)
OD of catheter:	
Length of catheter:	6 mm, 9 mm
Tip of catheter:	Beveled (b)(4)
Introducer needle:	304 Stainless
ID of needle:	(b)(4)
OD of needle:	
Tip of needle:	(b)-Bevel
Proximal end configuration:	Proprietary Tubing Connector
Tubing connector needle:	(b) gauge
ID:	(b)(4)
OD:	
Length:	0.230 in.
Tubing composition:	Polyurethane (outer); Polyethylene (inner)

e. Mechanical specifications: The infusion set is designed and will be tested to exceed the following mechanical requirements:

i. Flow test (b)(4)
ii. Leak test (b)(4)
iii. Pull tests:

Stainless steel cannula to hub	(b)(4)
Teflon catheter to hub	(b)(4)
Tubing to tubing connector	
Tubing to "press and turn" connector	

f. Biological specifications

i. ISO 10993 determination: The Paradigm Quick-set meets ISO 10993 biocompatibility standards.

ii. Biocompatibility evaluations: The Paradigm Quick-set infusion set is made of many of the same materials as the predicate device, which meets ISO 10993 standards for device biocompatibility.

g. Chemical specifications

i. (b)(4)

ii. (b)(4)

(b)(4)

h. Product specification: The product specification is included in Appendix 1. A risk analysis is included in Appendix 7.

5. Labels, Labeling and Advertisements

a. Package labels: Copies of the sterile pack and box labels for the device are included in Appendix 3.

b. Instructions for Use: A copy of the device Instructions for Use is included in Appendix 4.

c. Promotional materials: No promotional material has been developed for this device at this time.

6. Photographs

Photographs of the device are included in Appendix 5.

7. Engineering Drawings

Engineering drawings are included in Appendix 6.

8. Class III Summary

Not applicable. The device is not a Class III device.

9. Performance Standards

To the best of our knowledge and understanding, no performance standards have been established for devices of this type under section 514 of the Act. However, the device or components have been designed to conform to the following U.S. and international standards to the extent practicable:

U.S. Quality System Regulation; 21 CFR 820;

EN 46001: Quality Systems - Medical Devices - Particular requirements for the application of ISO 9001;

ISO 9001: Quality Systems: Model for quality assurance in design, development, production, installation and servicing;

93/42/EEC: Council Directive of 14 June 1993 concerning medical devices;

(b)(4)

EN 556: Sterilization of medial devices - requirements for the devices to be labeled "Sterile";

ISO 10555: Sterile, single-use intravascular catheters;

ISO 10993-1: Biological evaluation of medical devices - Guidance on selection of tests;

ISO 10993-7: Biological evaluation of medical devices - Ethylene oxide sterilization residuals;

DIN 58362: Infusion equipment and accessories.

10. Performance Data

a. Bench data: The qualification test plan and report are included in Appendix 2.

b. Comparative claims: Any comparisons to other infusion sets will be limited to comparisons of product specifications.

c. Unique designs: The design of the infusion set is a modification of the design of the predicate device. The tubing connector is a unique design of MiniMed Inc.

d. Biocompatibility data: The administration set materials meet ISO 10993 specifications for biocompatibility.

e. Drug/device compatibility: The infusion set is intended to be used with insulin and any other medication suitable for infusion by an external pump. Drug device compatibility should not be expected to differ from the predicate device.

f. Drug stability: The stability of insulin for use with external infusion pump delivery systems is widely known and accepted. Insulin will be stored in a MiniMed subcomponent reservoir.

g. **Residual volume:** (b)(4)
(b)(4)
(b)(4)

11. Sterilization Information

(b)(4)

(b)(4)

g. Sterilizer information: (b)(4)

(b)(4)

(b)(4)

12. **Kit Certification Statement**

Not applicable.

13. **Guidance Document Issues**

Development of this submission has relied, in part, on HHS Publication FDA 95-4158, "Premarket Notification 510(k): Regulatory Requirements for Medical Devices." This premarket notification was also prepared with reference to the guidance document "Guidance on Premarket Notification [510(k)] Submissions for Short and Long-Term Intravascular Catheters". Labeling was developed in accordance with FDA's Device Labeling Guidance, Memorandum G91-1, dated March 8, 1991.

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Section G. Description of the Lawfully Marketed Equivalent Device

1. Device Trade or Proprietary Name

Maersk Medical Quick-set infusion set (originally submitted as the Maersk Medical Contour infusion set)

2. Device Common and Classification Name(s)

Common Name:	Subcutaneous Infusion Administration Set
Classification Name:	Intravascular Administration Set
	Fluid Delivery Tubing

3. Device Classification Information

Class:	II
Panel:	80
Product Code:	80FPA; 80FPK
Cite:	21 CFR 880.5440

4. Document Control Number(s)

K991759

5. Description of the Marketed Equivalent Device

(b)(4)

MAERSK

(b)(4)

The combination of two tubing lengths and two catheter lengths results in four models of the device:

Model Number	Tubing Length	Catheter Length
(b)(4)	43 in.	9 mm
	43 in.	6 mm
	23 in.	9 mm
	23 in.	6 mm

b. Use with other devices: The Quick-set is marketed exclusively by MiniMed Inc. for use with the following MiniMed products:

Model Number	"K" Number	Device Type
103/193	K991936	Medication reservoir
128	K975208	Polyfin® extension set
407C	K991013	Infusion Pump
505	K963948	Infusion pump
506	K901588	Insulin pump
507	K960001	Insulin pump
507C	K972107	Insulin pump
508	K990801	Insulin Pump
395	K992300	Quick-serter insertion device

®Polyfin is a Registered Trademark of MiniMed Inc.
™Quick-serter is a Trademark of MiniMed Inc.

c. Physical specifications

i. Components and materials: Following is a list of the principal components of the Quick-set infusion set:

Part Description	Material
Male Luer Cap	(b)(4)
Female Luer Hub	
Tubing	
Inside	
Outside	
Introducer needle hub	
Introducer needle	
Connector	
Lid	
Septum	
Catheter bushing	
Catheter	
Sealing ring	
Base piece	
Gasket	
Adhesive tape	
Introducer needle guard	
Dummy connector	

ii. Other materials: The materials listed below are also used in the fabrication of the device:

Material	Comments
Silicone oil	(b)(4)
UV Adhesive	

iii. Nominal dimensions:

ID of tubing:	(b)(4)
OD of tubing:	
Tubing length:	23 in. (58 cm); 43 in. (109 cm)
Number of lumens:	One
Shape of lumen:	Round

Tip configuration:	PTFE catheter over needle
ID of catheter:	(b)(4)
OD of catheter:	
Length of catheter:	6 mm; 9 mm
Tip of catheter:	Beveled (b)(4)
Introducer needle:	304 Stainless
ID of needle:	(b)(4)
OD of needle:	
Tip of needle:	(-Bevel
Proximal end configuration:	Luer connector
Tubing composition:	Polyurethane (outer); Polyethylene (inner)

d. Mechanical specifications: The Quick-set infusion set is designed and tested to exceed the following mechanical requirements:

(b)(4)

e. Biological specifications: The administration set materials meet ISO 10993 specifications for biocompatibility.

f. Chemical specifications

(b)(4)

6. Intended Use of the Marketed Equivalent Device

The Quick-set infusion set is intended for the subcutaneous infusion of medication, including insulin, from an external infusion pump.

MAERSK

7. Labels and Labeling

Sterile pack and box labels of the predicate device are included in Appendix 9. A copy of the Quick-set Instructions for Use is included in Appendix 10.

MAERSK

Section H. Comparison of the New and Existing Devices

(b)(4)

MAERSK

4. Table of Comparison

(b)(4)

MAERSK

Section I. Appendices

1. Product Specification: Paradigm Quick-set Infusion Set
2. Qualification Plan and Report: Paradigm Quick-set Infusion Set
3. Sterile Pack and Box Labels: Paradigm Quick-set Infusion Set
4. Instructions for Use: Paradigm Quick-set Infusion Set
5. Photographs: Paradigm Quick-set Infusion Set
6. Engineering Drawings: Paradigm Quick-set Infusion Set
7. Risk Analysis: Paradigm Quick-set Infusion Set
8. Material Matrix: Paradigm Quick-set Infusion Set
9. Sterile Pack and Box Labels: Quick-set Infusion Set
10. Instruction for Use: Quick-set Infusion Set

MAERSK

Appendix 1. Product Specification: Paradigm Quick-set Infusion Set

MAERSK

Product Specification: Paradigm Quick-set Infusion Set

ID of tubing:	(b)(4)
OD of tubing:	
Tubing length:	23 in.; 43 in.
Number of lumens:	One
Shape of lumen:	Round
Tip configuration:	PTFE catheter over needle
ID of catheter:	(b)(4)
OD of catheter:	
Length of catheter:	6 mm, 9 mm
Tip of catheter:	Beveled (b)(4)
Introducer needle:	304 Stainless
ID of needle:	(b)(4)
OD of needle:	
Tip of needle:	(-Bevel
Proximal end configuration:	Proprietary Tubing Connector
Tubing connector needle:	(b gauge
ID:	(b)(4)
OD:	
Length:	
Tubing composition:	Polyurethane (outer); Polyethylene (inner)

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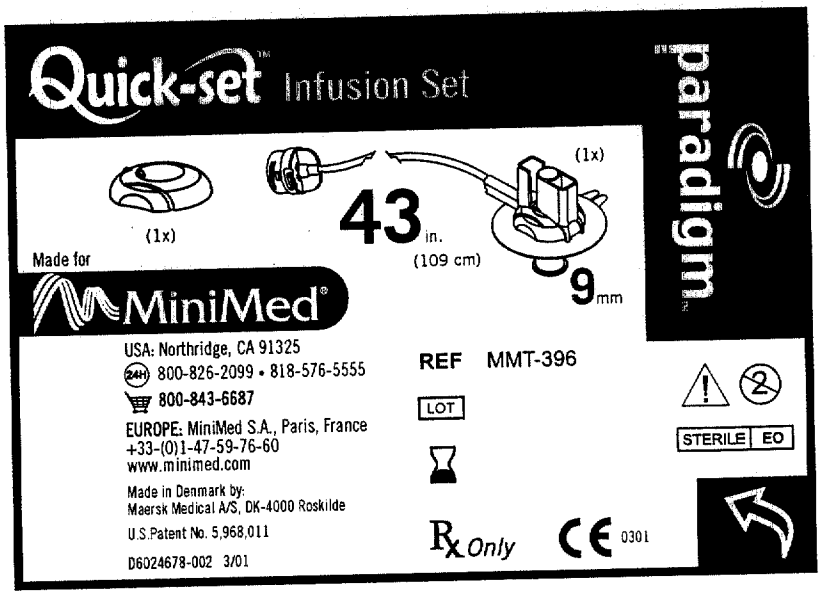
Appendix 2. Qualification Plan and Report: Paradigm Quick-set Infusion Set

(b)(4),Testing Data

MAERSK

Appendix 3. Sterile Pack and Box Labels: Paradigm Quick-set Infusion Set

LID LABELS



VENDOR TO USE ELECTRONIC FILE
DMP6024678-002 REV C

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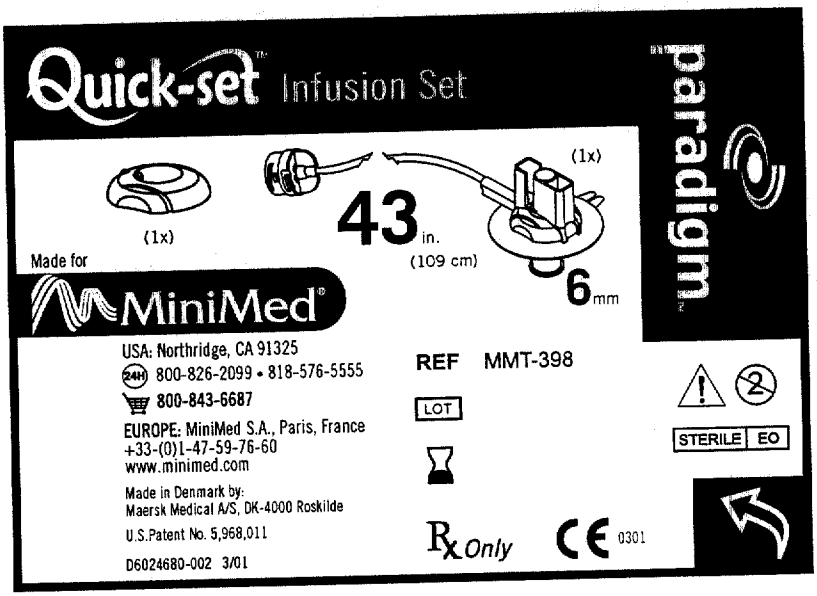
LID LABELS



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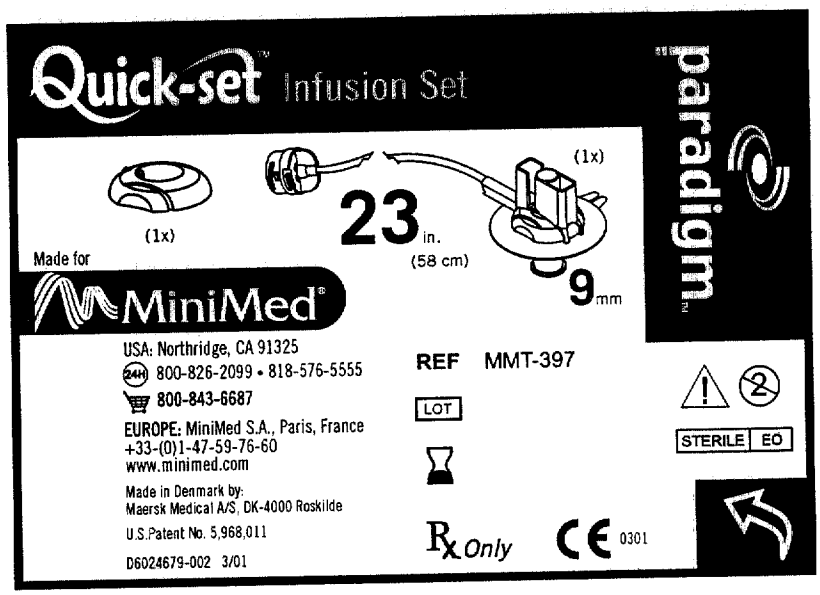
DMP6024680-002 REV C

LID LABELS



VENDOR TO USE ELECTRONIC FILE
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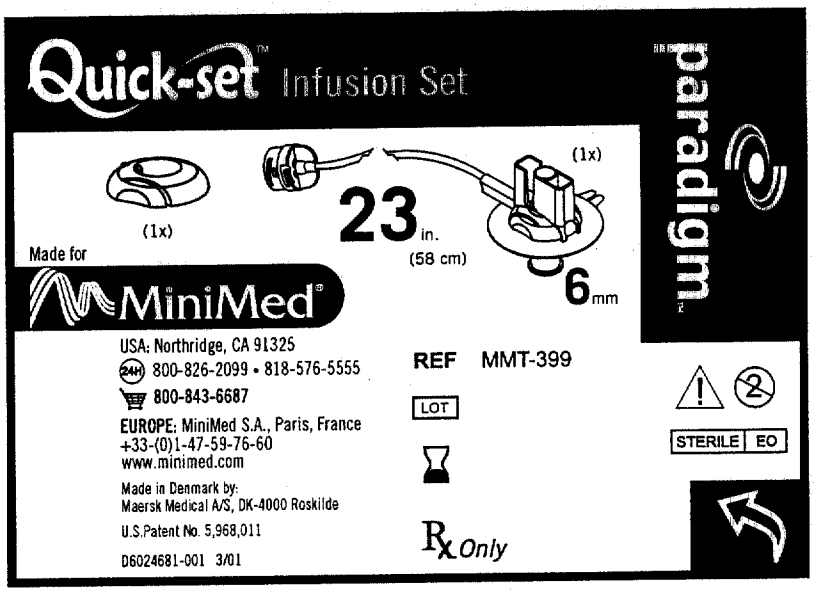
LID LABELS



VENDOR TO USE ELECTRONIC FILE
DMP6024681-001 REV C

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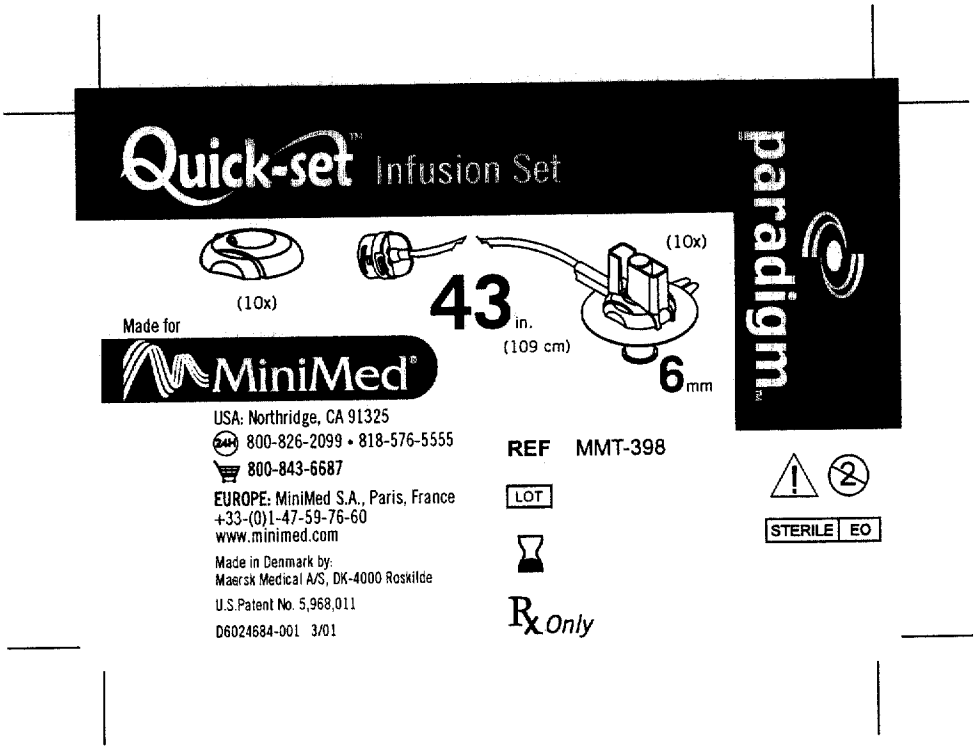
BOX LABEL



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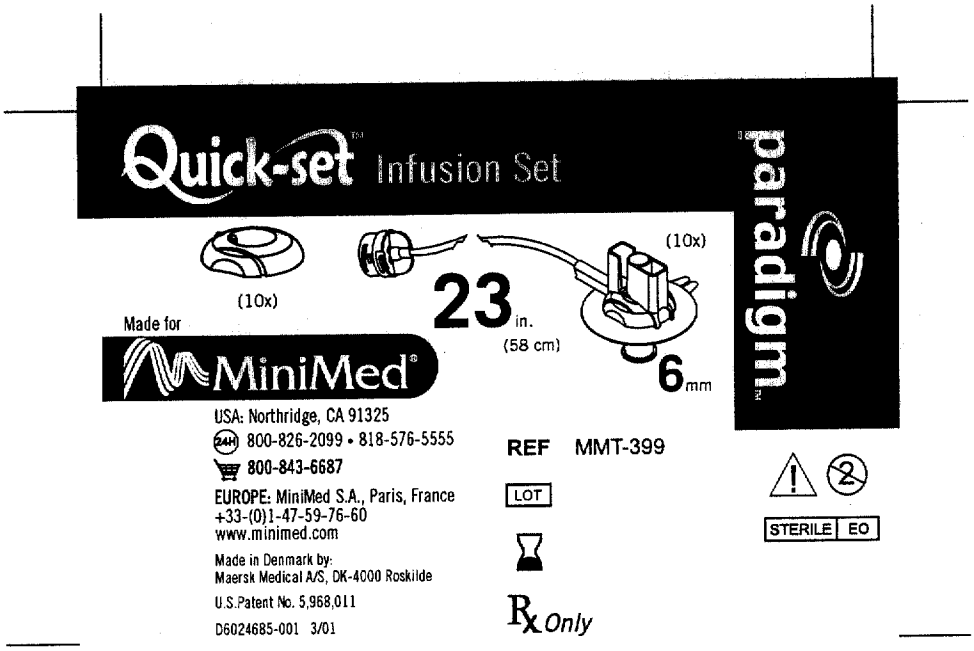
BOX LABEL



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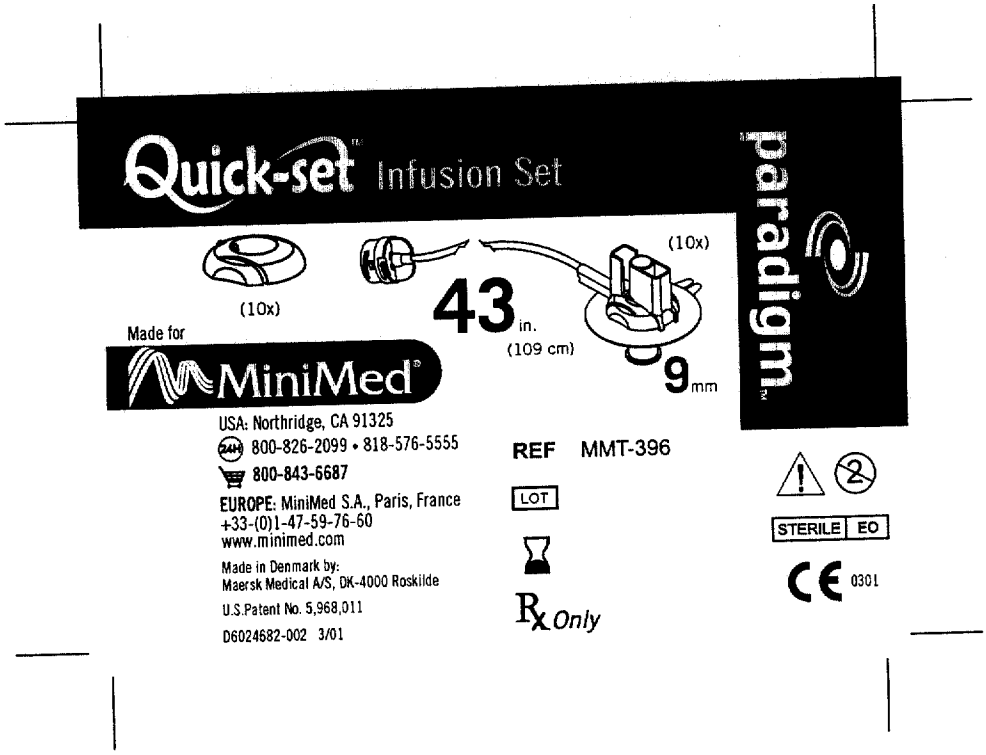
BOX LABEL



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DMP6024682-002 REV C

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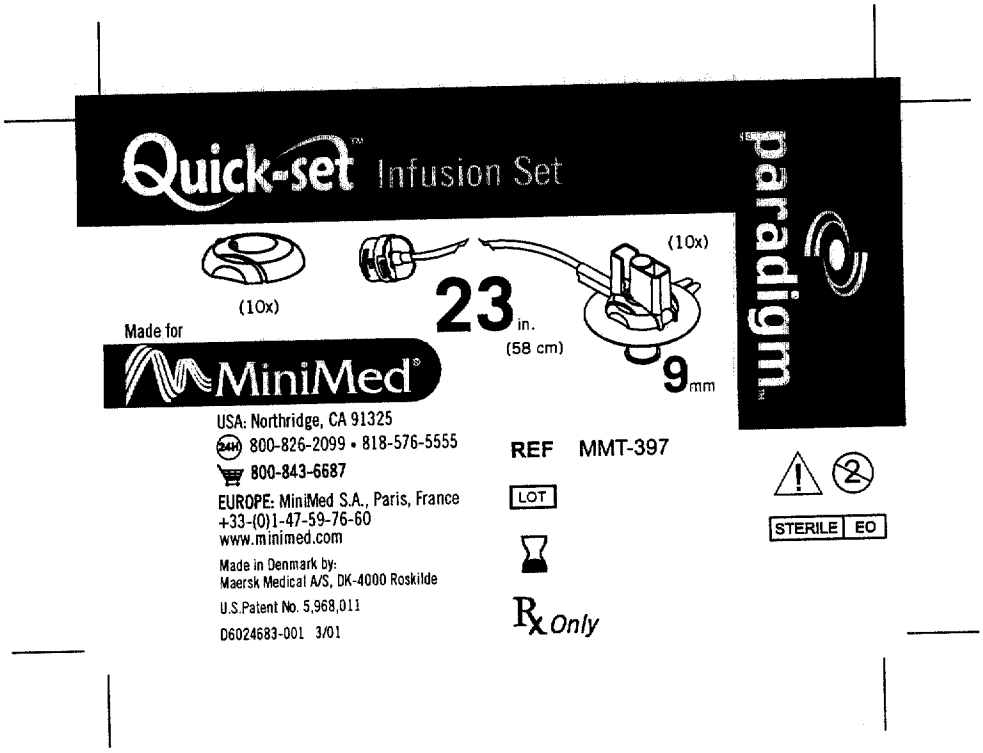
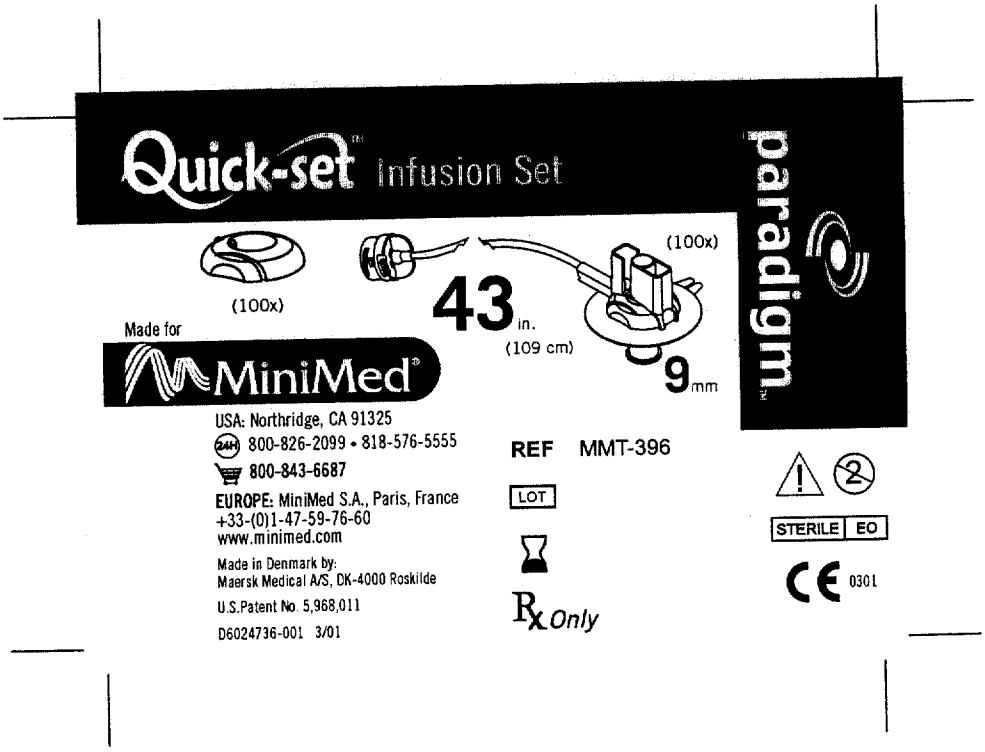
BOX LABEL



VENDOR TO USE ELECTRONIC FILE
DMP6024683-001 REV C

SHIPPER LABEL



VENDOR TO USE ELECTRONIC FILE
DMP6024736-001 REV A

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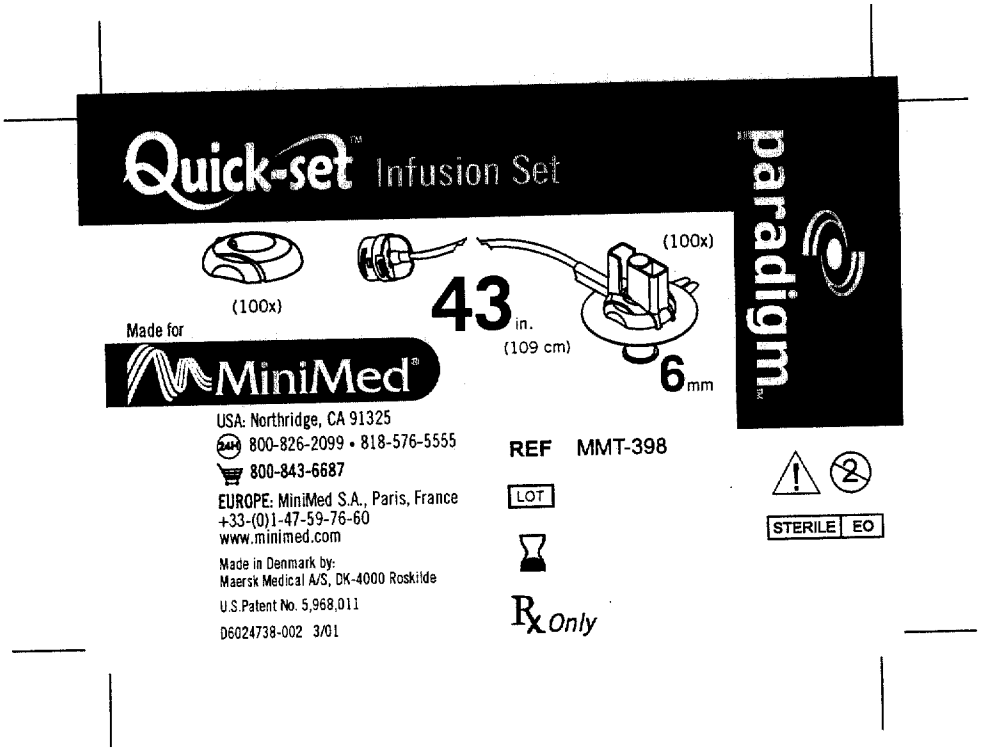
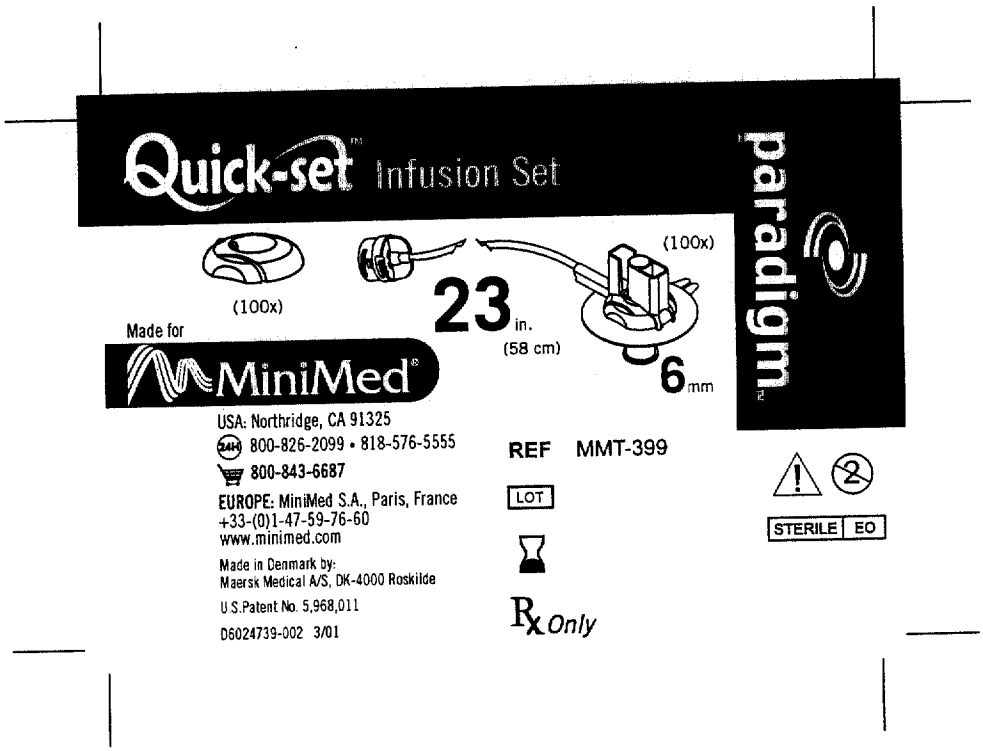
SHIPPER LABEL



VENDOR TO USE ELECTRONIC FILE
DMP6024738-002 REV -

SHIPPER LABEL



VENDOR TO USE ELECTRONIC FILE
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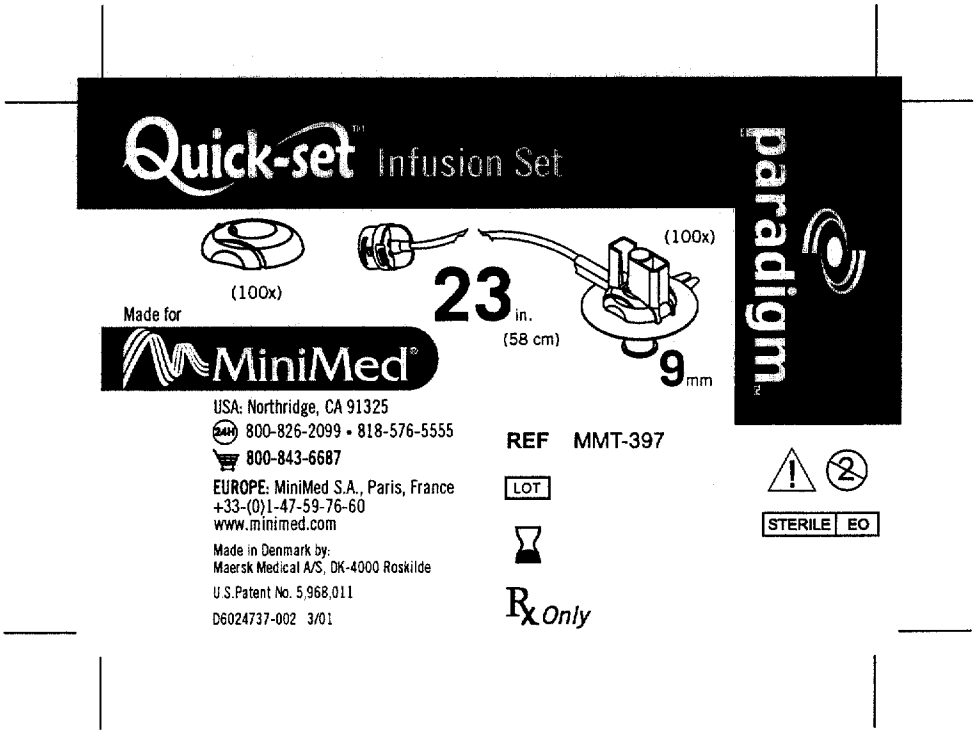
SHIPPER LABEL



VENDOR TO USE ELECTRONIC FILE
DMP6024737-002 REV -

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MAERSK

Appendix 4. Instructions for Use: Paradigm Quick-set Infusion Set

The Quick-set is made for MiniMed by:
Maersk Medical A/S, DK-4000, Roskilde, Denmark.

The Quick-serter is made by:
MiniMed Inc., Northridge, CA.

MiniMed

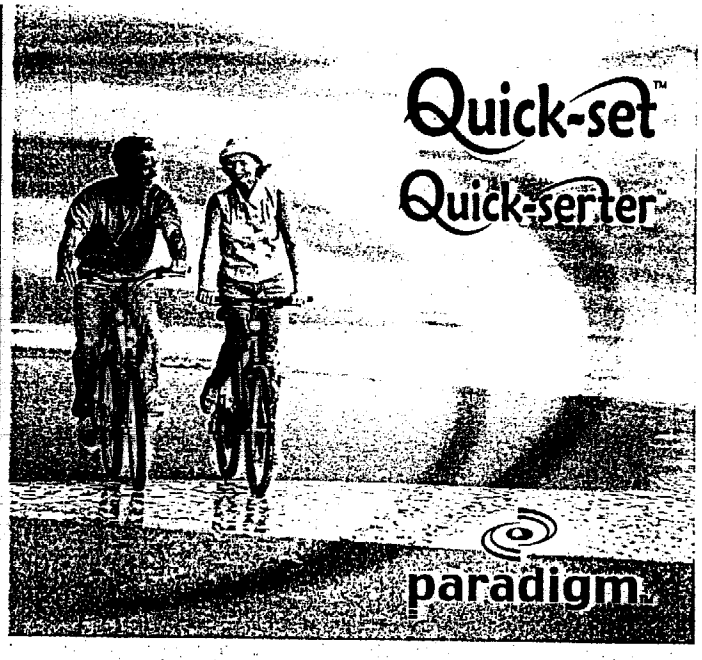
EUROPE: MiniMed S.A., Pa
+33-(0)1-47-59-76-60
USA: Northridge, CA
+1-818-576-5555
www.minimed.com

CE 0301 / Quick

CE 0459 / Quick

D9196137-021 2/01

MiniMed



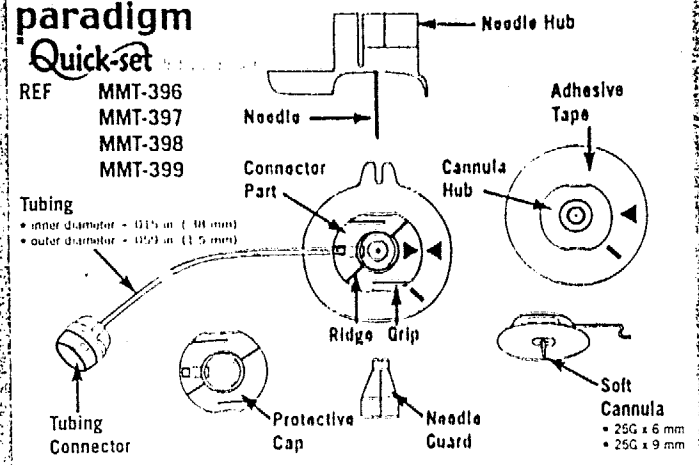
Quick-set™

Quick-serter™

paradigm

paradigm
Quick-set

REF MMT-396
MMT-397
MMT-398
MMT-399



Maintenance

Clean the Quick-serter with soapy water, using liquid detergent or other household soaps.

Disinfect the Quick-serter with a 9% bleach solution or 70% isopropyl alcohol.

Store your Quick-serter in the released position to maintain optimum product performance and life.

Meaning of Symbols

- Do Not Re-Use this Device
- Attention, See Instructions For Use
- Sterilized using Ethylene Oxide
- REF — Reference/Model Number
- Date of Manufacture
- LOT — Lot Number
- Open Here
- Use By

Warnings (continued)

Replace the Paradigm Quick-set if the tape becomes loose, because the soft cannula may be halfway out or dislodged.

If you are infusing insulin, do not change your infusion set just prior to bedtime, unless blood sugar can be checked 1-3 hours after insertion.

Do not put disinfectants, perfumes, or deodorants on your infusion set, as these may affect the integrity of the set.

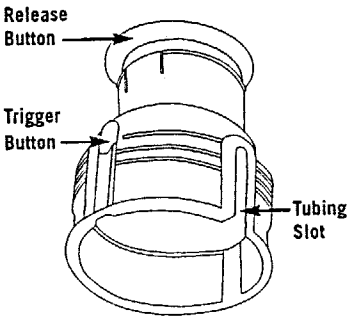
Never prime the set or attempt to free a clogged line while the infusion set is inserted. You may accidentally inject too much medication.

Do not re-insert the introducer needle into the infusion set. Re-insertion could cause tearing of the soft cannula which would result in unpredictable medication flow.

Never use the infusion set for more than 72 hours.

Quick-serter Infusion Set Insertion System

REF MMT-395



The Quick-serter is a device used to insert the Paradigm Quick-set.

Table of Contents

User Guide

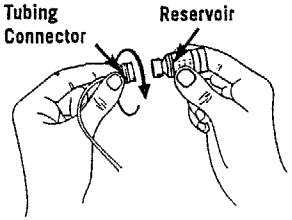
MiniMed

Priming the Paradigm Quick-set

Read this *User Guide* carefully before handling the Paradigm Quick-set.

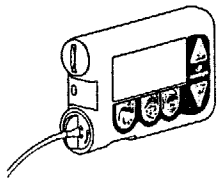
Do the first set-up with your healthcare provider present if using the Paradigm Quick-set for the first time.

Step 1



Attach tubing connector to filled reservoir, and rotate connector $^1/_4$ turn until it snaps in place.

Step 2



Rewind pump and properly install the reservoir per Paradigm pump User Guide.

Warnings

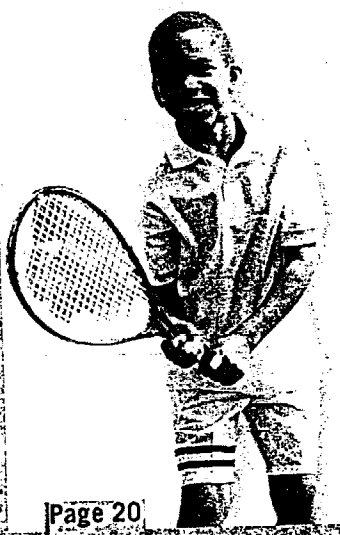
If you are infusing insulin, and your blood glucose level becomes high, or an "occlusion" alarm occurs, check for clogs and leaks. If in doubt, change the infusion set as the soft cannula could be dislodged or partially clogged. Test your blood glucose level again to make sure you have corrected the problem.

If blood glucose is still high, contact your physician immediately. If your physician is not available, inject insulin manually per your physician's recommendation.

Check frequently to make sure the soft cannula remains firmly in place as you may not notice any pain if it pulls out. The soft cannula must always be completely inserted so that you receive the full amount of medication.

Do not leave air in infusion set. Prime completely.

If the infusion site becomes inflamed, replace the set and use a new site until the first site has healed.

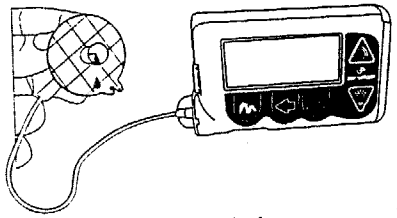


Precautions (continued)

To ensure your safety:

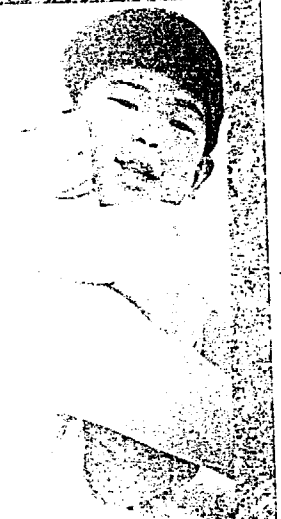
- Read the instructions and properly prepare the infusion site.
- Never point the loaded Quick-serter toward the face, eyes, or any other body part where insertion is not desired.
- Be sure the Paradigm Quick-set is secure in the Quick-serter, with the needle pointed straight ahead.
- Remove the needle guard before attempting to insert the Paradigm Quick-set.

Step 3



Run a manual prime (refer to Paradigm pump User Guide) until drop forms at end of needle.

Priming Volumes:
23in. (58.4cm) set = 10 units (U-100 insulin) or 0.10 ml
43in. (109.2cm) set = 18 units (U-100 insulin) or 0.18 ml

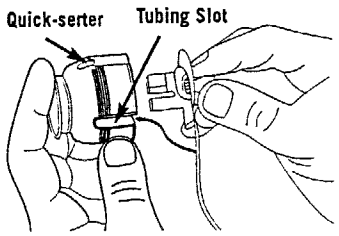


Inserting with the Quick-serter

Step 1

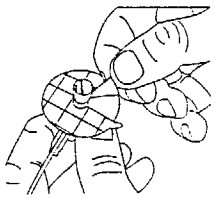
Select an infusion site as recommended by your healthcare provider. Infusion site should be thoroughly cleaned and allowed to dry before inserting Paradigm Quick-set.

Step 2



Align tubing with tubing slot and place into Quick-serter.

Step 3



Remove paper backing.

WARNING: If infusing insulin, check your blood glucose 1-to-2 hours after insertion. Re-check your blood glucose levels frequently, as advised by your healthcare provider.

Precautions

Use aseptic techniques when temporarily disconnecting the set.

If you are using insulin, preventing hyperglycemia is your responsibility. Discuss with your physician a plan of action for rapid replacement of insulin should your soft cannula become dislodged.

For subcutaneous use only, not for IV infusion.

Dispose of infusion set properly after single use. Do not clean or resterilize.

Always store infusion sets in a cool, dry place. Do not leave infusion sets in direct sunlight or the glove compartment of a car.

Replace the infusion set every 72 hours according to the Centers for Disease Control guidelines or per institutional protocol.

If the infusion set is not properly placed in the Quick-serter with the needle pointing straight ahead prior to insertion, pain or minor injury may occur. Do not re-use the infusion set if the needle has been damaged.

Contraindications

The Quick-serter is not indicated for use with infusion sets other than Quick-sets. MiniMed cannot guarantee this product's safety and/or efficacy if other infusion sets are used.

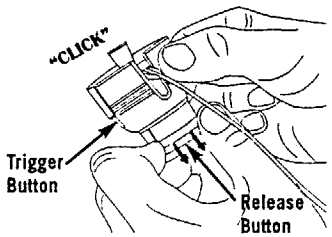
Prescription Device Notice

The Quick-serter is designed exclusively for use with the MiniMed Paradigm Quick-set infusion sets. U.S. law restricts Paradigm Quick-set infusion sets to sale by or on the order of a licensed physician.

Adverse Reactions

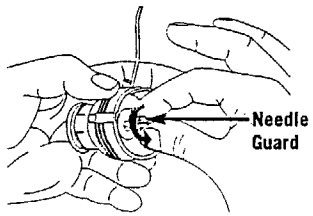
Failure to follow the directions may result in pain or injury. Please review the Precautions and Warnings included in this user guide before use.

Step 4



Pull back the release button until the Quick-serter "clicks" into place in the activated position.

Step 5



Twist to remove needle guard. Save for later use.
(See step 4 on page 15.)

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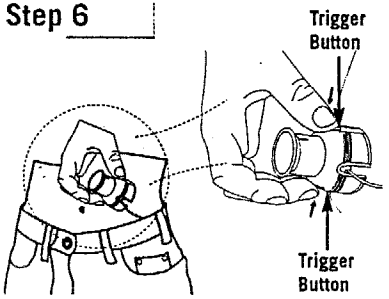
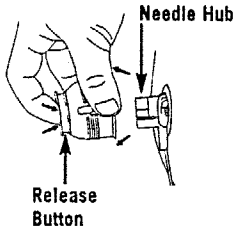
Step 6



Place Quick-serter over the infusion site, and push the two white trigger buttons at same time to release and insert the set.

Step 7



Press release button to detach Quick-serter, and lift from needle hub. Smooth down adhesive.

User Safety

Sterile Device

This device is sterile and non-pyrogenic unless the package has been opened or damaged. Do not use if the sterile package has been opened or damaged. The Paradigm Quick-set is a single-use device.

Indications for Use

The Paradigm Quick-set is intended for use with the MiniMed Paradigm pump and reservoir. The Paradigm Quick-set is intended for subcutaneous infusion of medicine, including insulin, from a Paradigm infusion pump.

The Quick-serter is indicated as an aid for insertion of the MiniMed Paradigm Quick-set infusion sets.

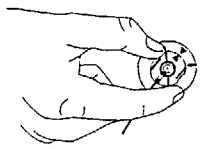
Reconnecting the Paradigm Quick-set

Step 1

Before reconnecting:

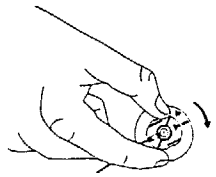
- Remove needle guard from connector part
- Remove protective cap from cannula hub
- Run a manual prime until drop is visible at connector part

Step 2



Gently hold ridges of connector part, and place onto cannula hub with triangles aligned.

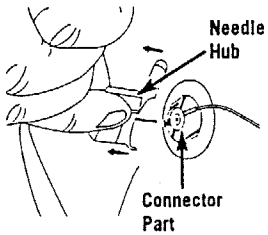
Step 3



Rotate connector part until you hear or feel a "click"and triangle aligns with line.

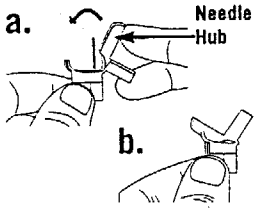
WARNING:
Check frequently to make sure the soft cannula remains in place.

Step 8



Gently pull blue needle hub away from connector part.

Step 9



Fold needle hub until it snaps into place, and dispose into sharps container.

Step 10

Fill the empty space in the cannula, by running the following fixed primes:

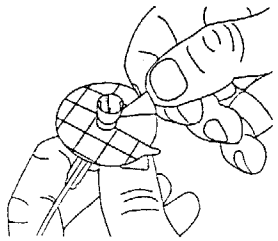
U-100
9mm: 0.5u (0.005 ml)
6mm: 0.3u (0.003 ml)

Inserting Manually

Step 1

Select an infusion site as recommended by your healthcare provider. Infusion site should be thoroughly cleaned and allowed to dry before inserting the Paradigm Quick-set.

Step 2

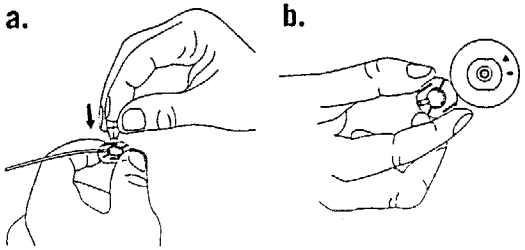


Remove paper backing.

WARNING: If infusing insulin, check your blood glucose 1-to-2 hours after insertion. Re-check your blood glucose levels frequently, as advised by your healthcare provider.

Step 4

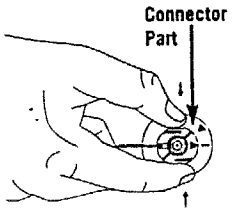
a. **b.**



For storage purposes,
a) insert needle guard into connector part, and
b) place protective cap on cannula hub.

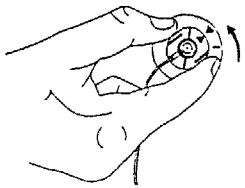
Disconnecting the Paradigm Quick-set

Step 1



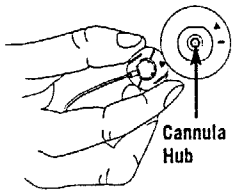
Gently squeeze grips of connector part.

Step 2



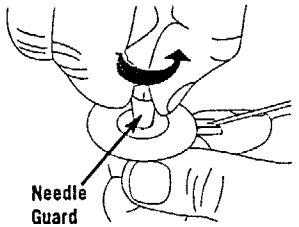
Rotate connector part to align triangles.

Step 3



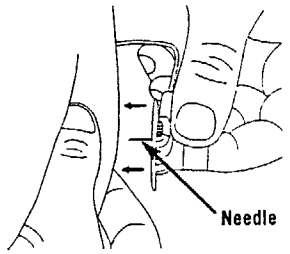
Lift off connector part from cannula hub.

Step 3



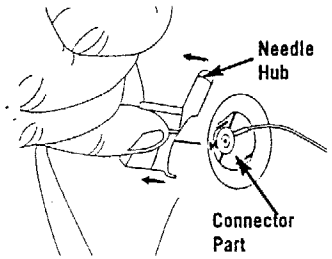
Twist to remove needle guard. Save for later use. (See step 4 on page 15.)

Step 4



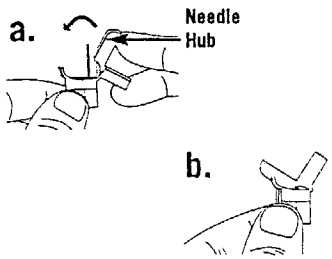
Pinch skin and insert the Paradigm Quick-set at a 90° angle. Smooth down adhesive.

Step 5



Gently pull blue needle hub away from connector part.

Step 6



Fold needle hub until it snaps into place, and dispose into sharps container.

WARNING: Check frequently to make sure the soft cannula remains in place.

Step 7

To fill the empty space in the cannula, run the following fixed primes:

U-100
9mm: 0.5u (0.005 ml)
6mm: 0.3u (0.003 ml)

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Appendix 5. Photographs: Paradigm Quick-set Infusion Set

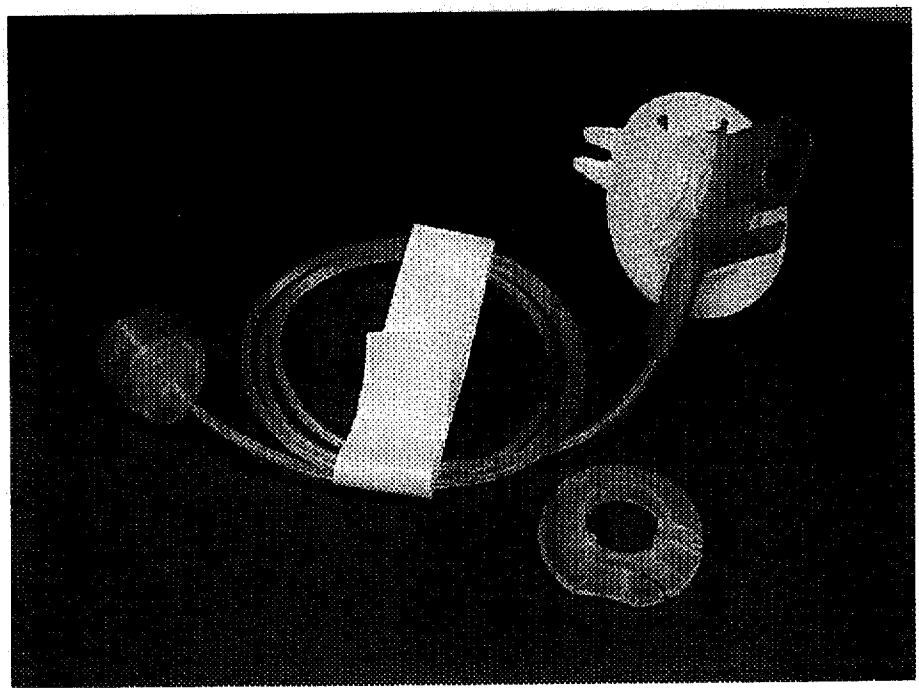

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Figure 1. Paradigm Quick-set Infusion Set

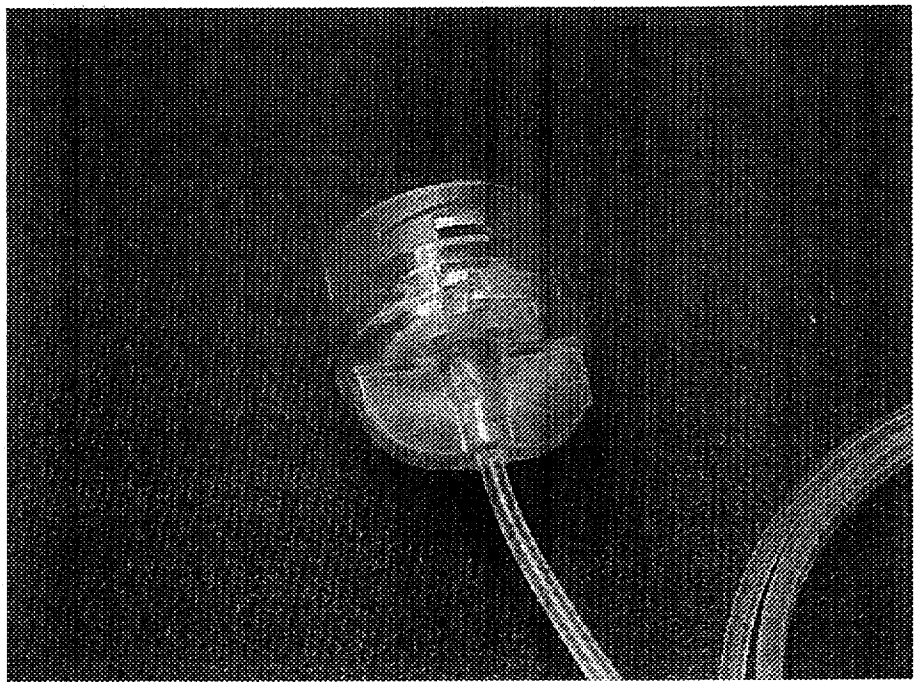

Figure 2. MiniMed Tubing Connector

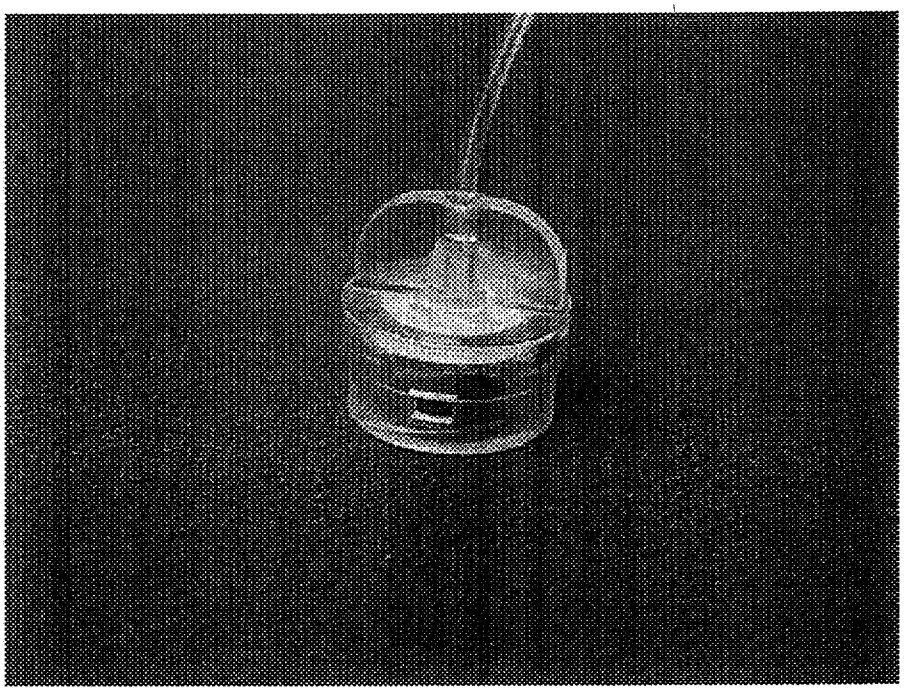

Figure 3. MiniMed Tubing Connector Side View

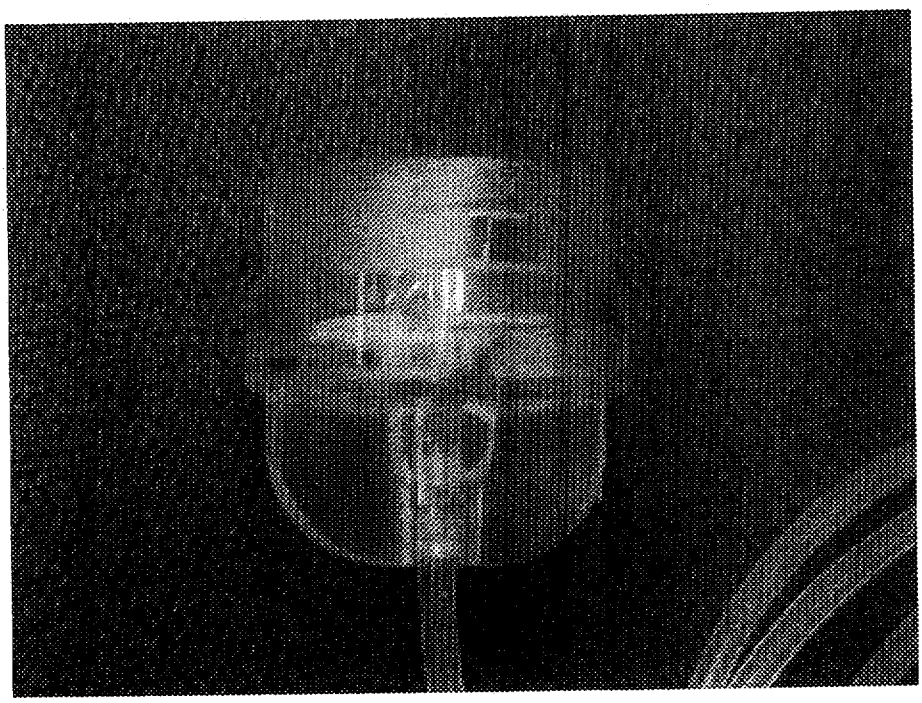

Figure 4. MiniMed Tubing Connector Side View

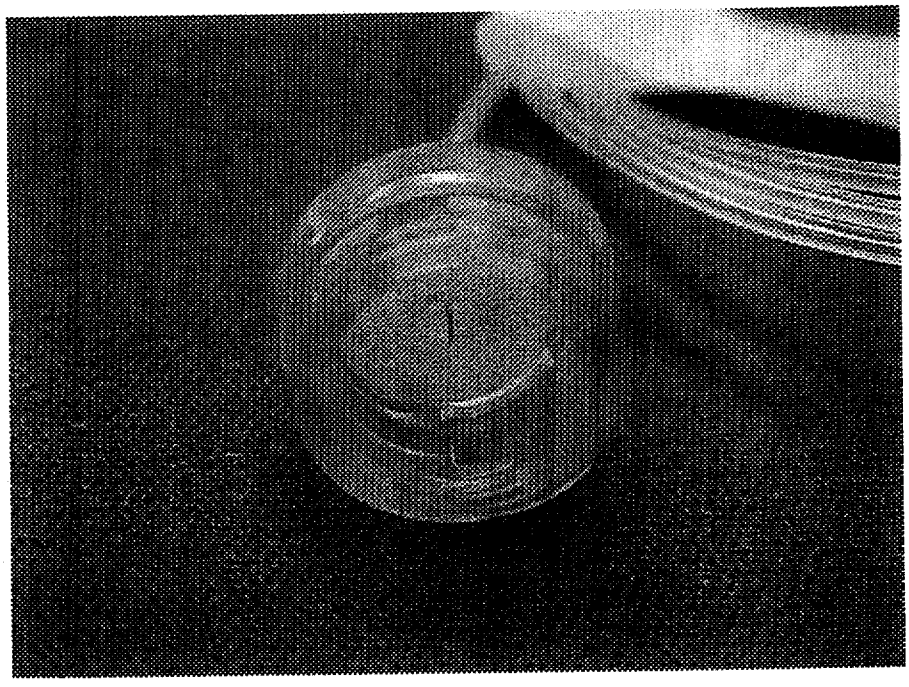

Figure 5. MiniMed Tubing Connector Needle for Fluid Path

100

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Appendix 6. Engineering Drawings: Paradigm Quick-set Infusion Set

(b)(4),Technical drawings

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Appendix 7. Risk Analysis: Paradigm Quick-set Infusion Set

(b)(4),Risk Management Plan

(b)(4),Risk Management Plan

(b)(4),Risk Management Plan

(b)(4),Risk Management Plan

(b)(4),Risk Management Plan

(b)(4),Risk Management Plan

(b)(4),Risk Management Plan

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Appendix 8. Material Matrix: Paradigm Quick-set Infusion Set

NO	Part Description	Material	Formulation	Contact Type
1	Tubing Connector			
2	Tubing			
	Inside			
	Outside			
3	Gasket			
4	Introducer needle			
5	Introducer needle hub			
6	Septum			
7	Lid			
8	Sealing ring			
9	Connector			
10	Adhesive tape			
11	Base piece			
12	Catheter bushing			
	Catheter			
13	Introducer needle guard			
14	Dummy connector			
15	Tubing connector needle			
16	Adhesive			
	Venting membrane			

(b)(4)

12

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Appendix 9. Sterile Pack and Box Labels: Quick-set Infusion Set

LID TABEL

Quick-set™ Infusion Set

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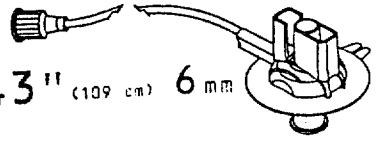

(1x) 43" (109 cm) 6 mm

(1x)

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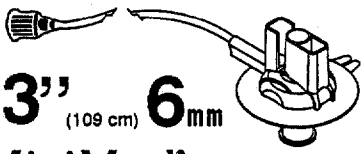

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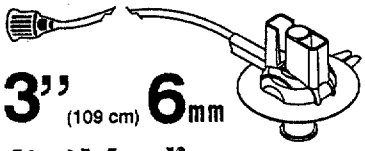

(100x) **43"** (109 cm) **6mm**

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STERILE EO

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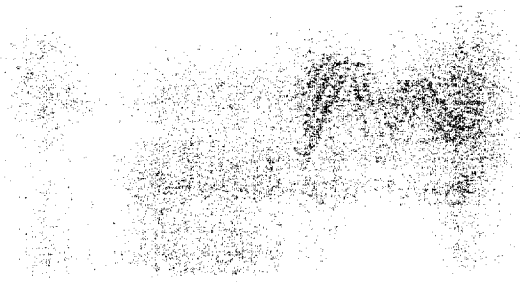
INNER/OUTER BOX TABEL



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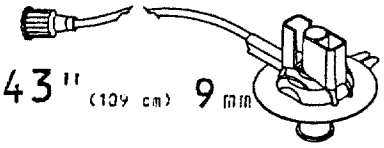
LID TABEL

Quick-set™ Infusion Set

CAUTION: U.S. law restricts this device to sale by, or on the order of a physician.



(1x) 43" (109 cm) 9 mm

(1x)

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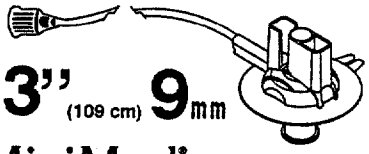

(10x) **43"** (109 cm) **9mm**

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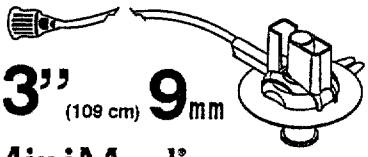

(100x) **43"** (109 cm) **9mm**

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INNER/OUTER BOX TABEL

LID TABEL

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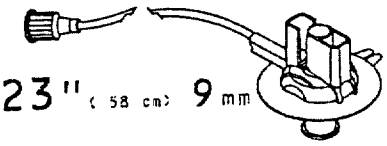

(1x) 23" (58 cm) 9 mm

(1x)

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Quick-set™ Infusion Set

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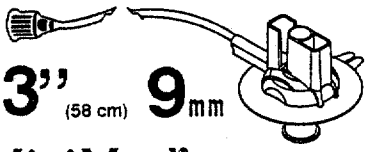

(10x) **23"** (58 cm) **9mm**

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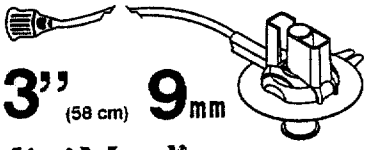

(100x) **23"** (58 cm) **9mm**

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INNER / OUTER BOX TABEL

LID TABEL

Quick-set™ Infusion Set

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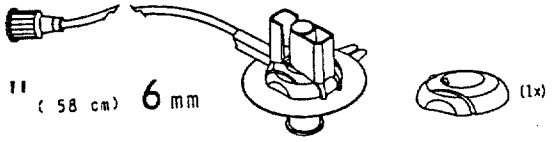

(1x) 23" (58 cm) 6 mm

(1x)

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STERILE EO CE 0301

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Quick-set™ Infusion Set

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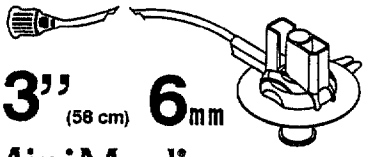

(10x) **23"** (58 cm) **6mm**

(10x)

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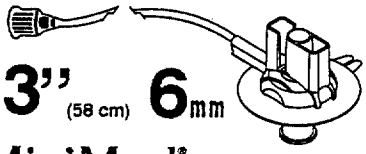

(100x) **23"** (58 cm) **6mm**

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INNER/OUTER BOX TABEL

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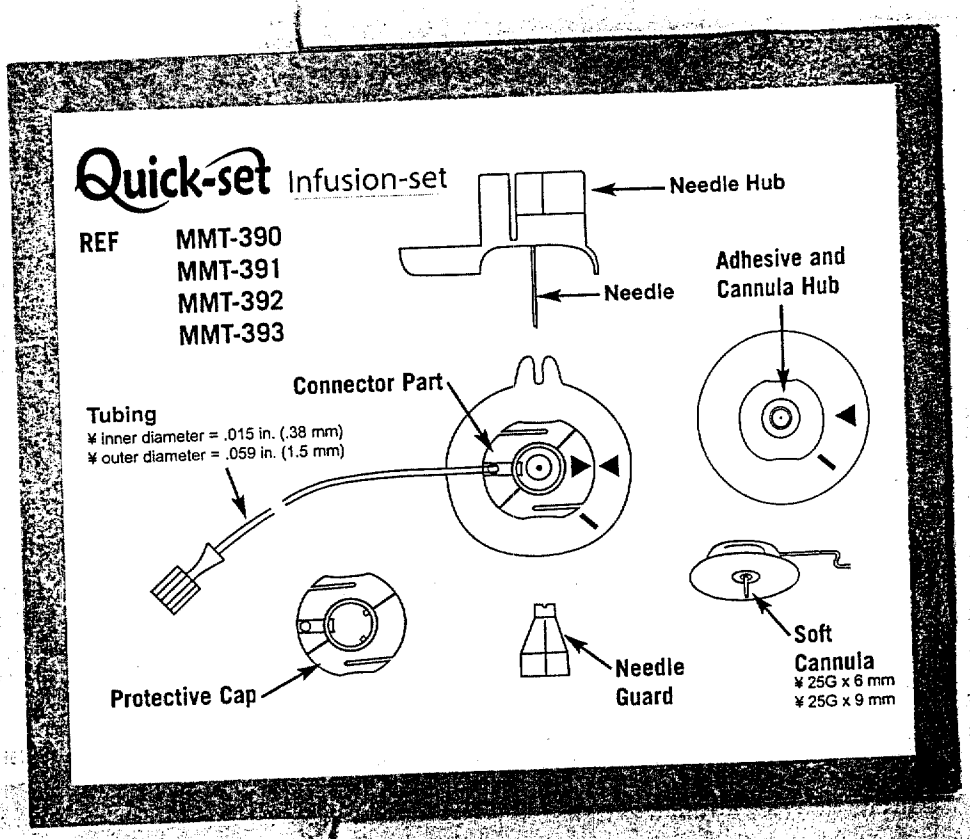
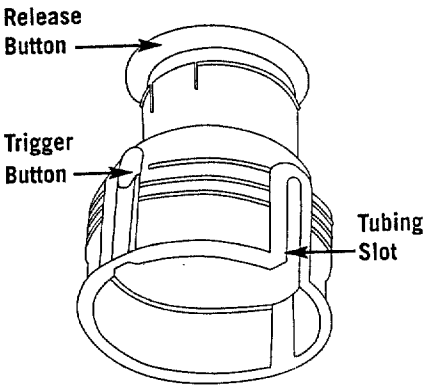
Appendix 10. Instruction for Use: Quick-set Infusion Set


Quick-set™
Quick-serter™
User Guide
MiniMed®


Quick-set Infusion-set
REF
MMT-390
MMT-391
MMT-392
MMT-393
Needle Hub
Needle
Adhesive and
Cannula Hub
Connector Part
Tubing
¥ inner diameter = .015 in. (.38 mm)
¥ outer diameter = .059 in. (1.5 mm)
Protective Cap
Needle
Guard
Soft
Cannula
¥ 25G x 6 mm
¥ 25G x 9 mm

Quick-serter Infusion Set Insertion System

REF MMT-395



The Quick-serter is a device used to insert the Quick-set.

Table of Contents

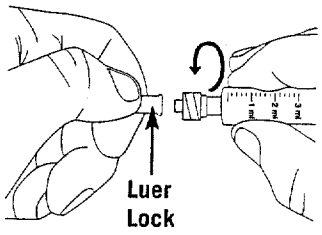
User Guide

MiniMed®

Priming the Quick-set

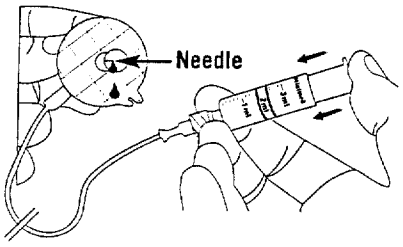
Read this *User Guide* carefully before handling the Quick-set. Do the first set-up with your health-care provider present if using the Quick-set for the first time.

Step 1



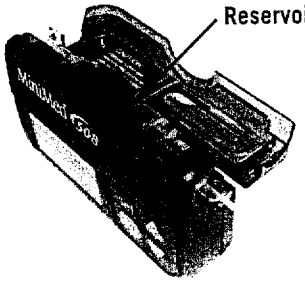
Attach luer lock to reservoir.

Step 2



To prime, press down reservoir plunger. Stop when you see drops at end of needle.

Step 3



Place reservoir in pump and run the following bolus prime:
U-100: 0.5u (0.005 ml)

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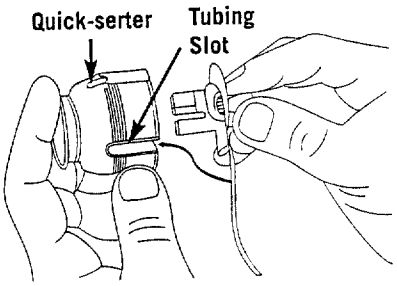
Inserting with the Quick-serter

Step 1

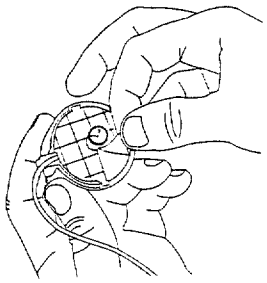
Select an infusion site as recommended by your healthcare provider. Infusion site should be thoroughly cleaned and allowed to dry before inserting Quick-set.

Step 2



Align tubing with tubing slot and place into Quick-serter.

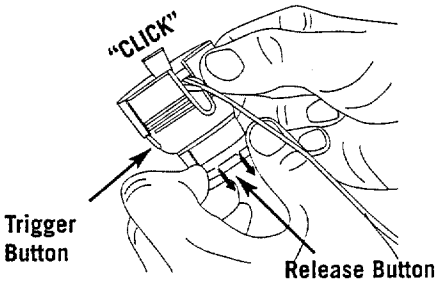
Step 3



Remove paper backing.

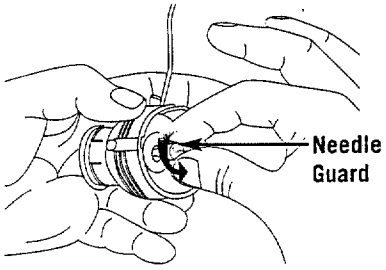
WARNING: If infusing insulin, check your blood glucose 1-to-2 hours after insertion. Re-check your blood glucose levels frequently, as advised by your healthcare provider.

Step 4



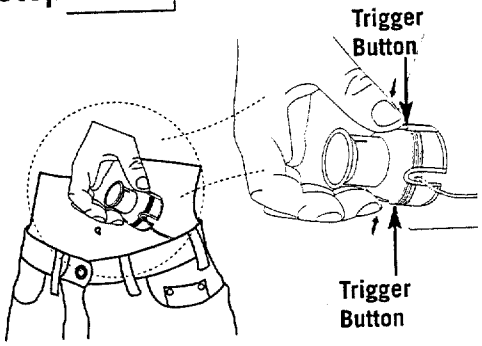
Pull back the release button until the Quick-serter "clicks" into place in the activated position.

Step 5



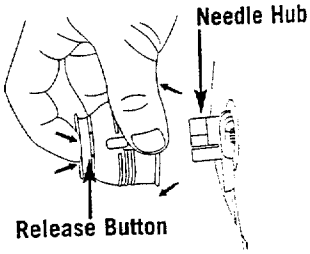
Twist to remove needle guard. Save for later use.
(See step 4 on page 15.)

Step 6



Place Quick-serter over the infusion site, and push the two white trigger buttons at same time to release and insert the set.

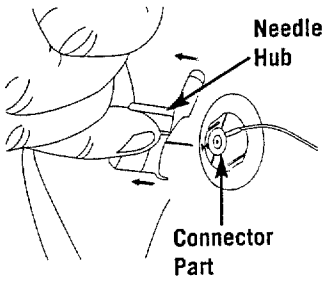
Step 7



Press release button to detach Quick-serter, and lift from needle hub. Smooth down adhesive.

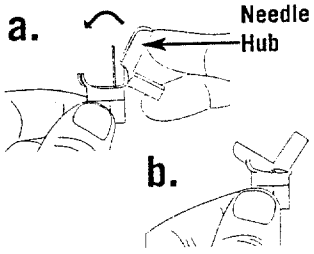
WARNING:
Check frequently to make sure the soft cannula remains in place.

Step 8



Gently pull blue needle hub away from connector part.

Step 9



Fold needle hub until it snaps into place, and dispose into sharps container.

Step 10

Fill the empty space in the cannula, by running the following fixed primes:

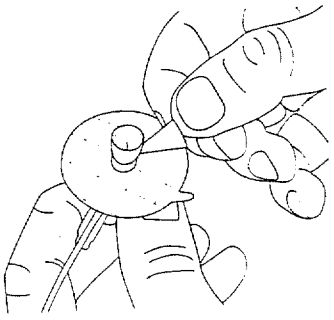
U-100
9mm: 0.5u (0.005 ml)
6mm: 0.3u (0.003 ml)

Inserting Manually

Step 1

Select an infusion site as recommended by your healthcare provider. Infusion site should be thoroughly cleaned and allowed to dry before inserting Quick-set.

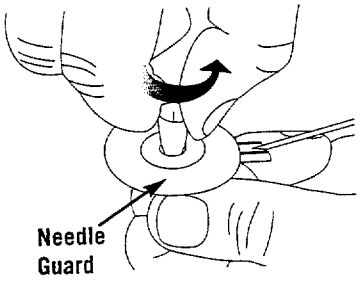
Step 2



Remove paper backing.

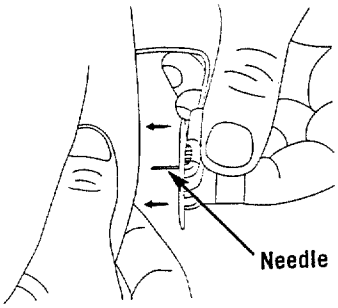
WARNING: If infusing insulin, check your blood glucose 1-to-2 hours after insertion. Re-check your blood glucose levels frequently,

Step 3



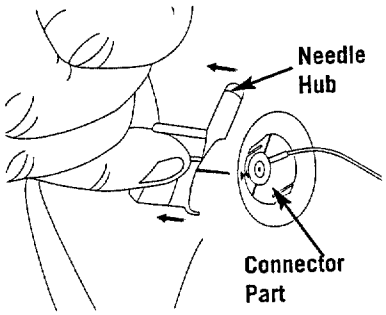
Twist to remove needle guard. Save for later use. (See step 4 on page 15.)

Step 4



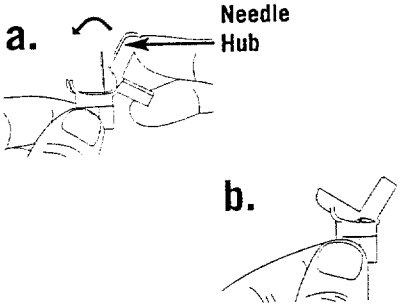
Pinch skin and insert the Quick-set at a 90° angle. Smooth down adhesive.

Step 5



Gently pull blue needle hub away from connector part.

Step 6

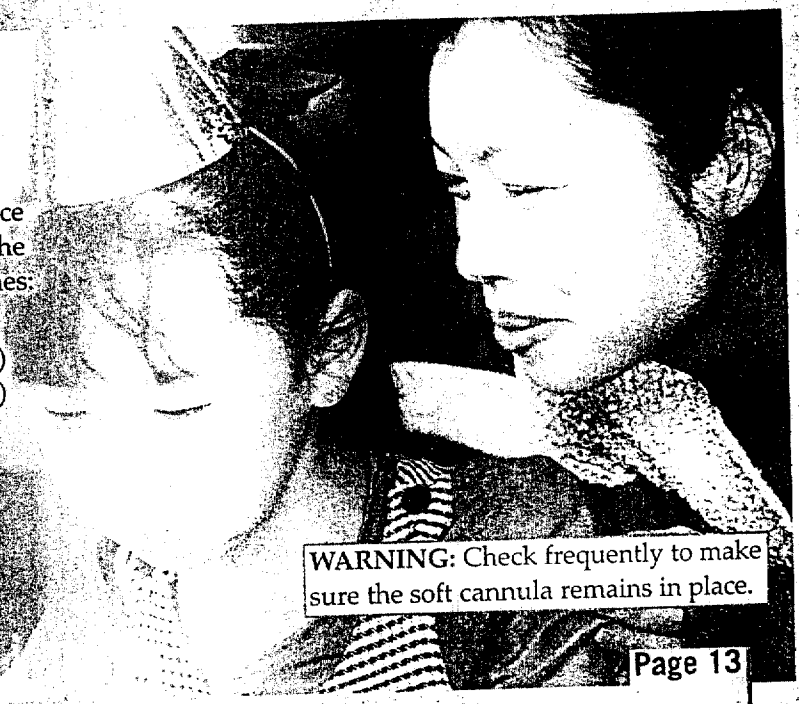


Fold needle hub until it snaps into place, and dispose into sharps container.

Step 7

To fill the empty space in the cannula, run the following fixed primes:

U-100
9mm: 0.5u (0.005 ml)
6mm: 0.3u (0.003 ml)



WARNING: Check frequently to make sure the soft cannula remains in place.

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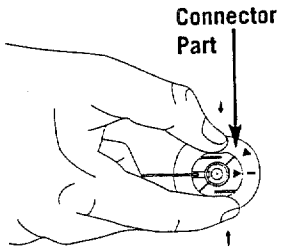
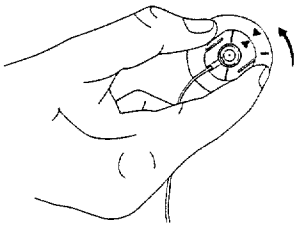
Disconnecting the Quick-set

Step 1



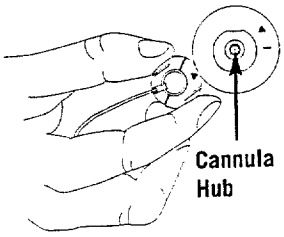
Gently squeeze grips of connector part.

Step 2



Rotate connector part to align triangles.

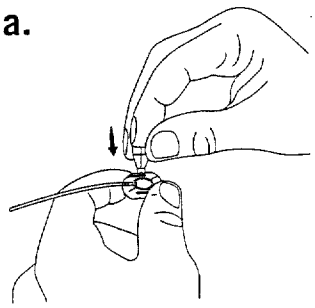
Step 3



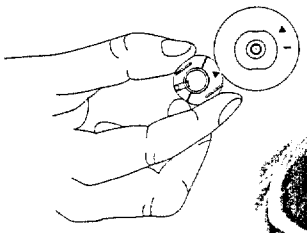
Lift off connector part from cannula hub.

Step 4

a.



b.



For storage purposes,
a) insert needle guard into connector part, and
b) place protective cap on cannula hub.

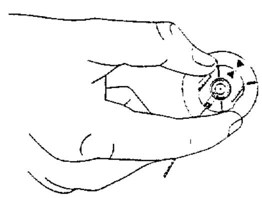
Reconnecting the Quick-set

Step 1

Before reconnecting:

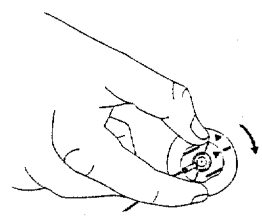
- Remove needle guard from connector part
- Remove protective cap from cannula hub
- Run a prime until drop is visible at connector part

Step 2



Gently hold ridges of connector part, and place onto cannula hub with triangles aligned.

Step 3



Rotate connector part until you hear or feel a "click" and triangle aligns with line.

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User Safety

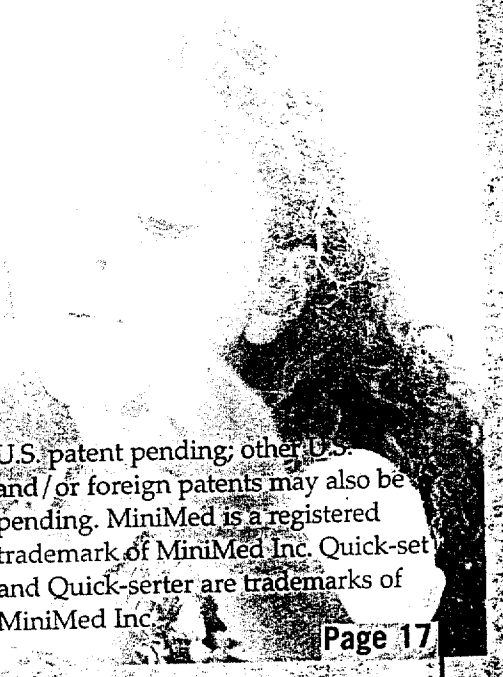
Sterile Device

The Quick-set is sterile and non-pyrogenic unless the package has been opened or damaged. Do not use if the sterile package has been opened or damaged. The Quick-set is a single-use device.

Indications for Use

The Quick-set and Quick-serter are intended for use with MiniMed pumps and MiniMed reservoirs. The Quick-set is intended for subcutaneous infusion of medicine, including insulin, from an external infusion pump.

The Quick-serter is indicated as an aid for insertion of the MiniMed Quick-set infusion sets.



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Contraindications

The Quick-set is contraindicated for the infusion of blood.

The Quick-serter is not indicated for use with infusion sets other than MiniMed Quick-sets. MiniMed cannot guarantee this product's safety and/or efficacy if other infusion sets are used.

Prescription Device Notice

The Quick-serter is designed exclusively for use with the MiniMed Quick-set infusion sets. U.S. law restricts the Quick-set infusion sets to sale by or on the order of a licensed physician.

Adverse Reactions

Failure to follow the directions may result in pain or injury. Please review the Precautions and Warnings included in these instructions before use.

Precautions

Use aseptic techniques when temporarily disconnecting the set.

If you are using insulin, preventing hyperglycemia is your responsibility. Discuss with your physician a plan of action for rapid replacement of insulin should your soft cannula become dislodged.

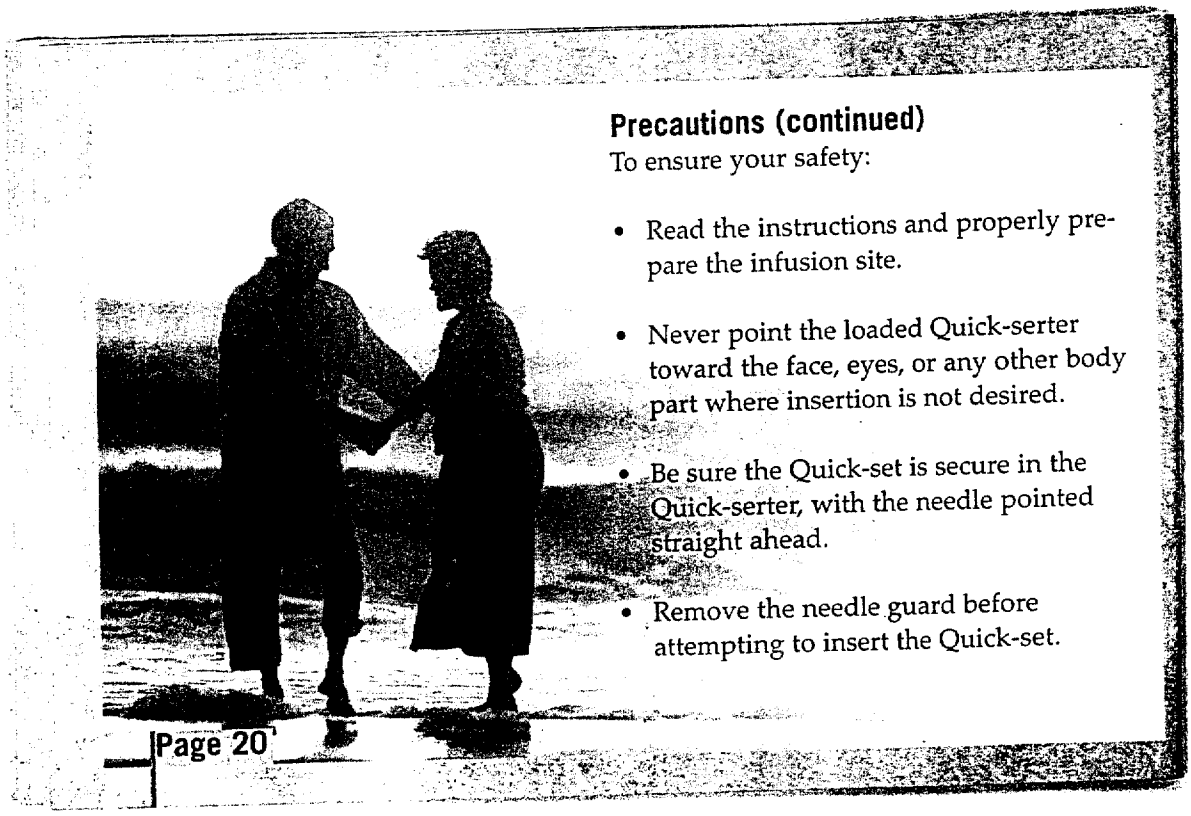
For subcutaneous use only, not for IV infusion.

Dispose of infusion set properly after single use. Do not clean or resterilize.

Always store infusion sets in a cool, dry place. Do not leave infusion sets in direct sunlight or the glove compartment of a car.

Replace the infusion set every 72 hours according to the Centers for Disease Control guidelines or per institutional protocol.

If the infusion set is not properly placed in the Quick-serter with the needle pointing straight ahead prior to insertion, pain or minor injury may occur. Do not re-use the infusion set if the needle has been damaged.


Precautions (continued)
To ensure your safety:
• Read the instructions and properly prepare the infusion site.
• Never point the loaded Quick-serter toward the face, eyes, or any other body part where insertion is not desired.
• Be sure the Quick-set is secure in the Quick-serter, with the needle pointed straight ahead.
• Remove the needle guard before attempting to insert the Quick-set.
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Warnings

If you are infusing insulin, and your blood glucose level becomes high, or an "occlusion" alarm occurs, check for clogs and leaks. If in doubt, change the infusion set as the soft cannula could be dislodged or partially clogged. Test your blood glucose level again to make sure you have corrected the problem.

If blood glucose is still high, contact your physician immediately. If your physician is not available, inject insulin manually per your physician's recommendation.

Check frequently to make sure the soft cannula remains firmly in place as you may not notice any pain if it pulls out. The soft cannula must always be completely inserted so that you receive the full amount of medication.

Do not leave air in infusion set. Prime completely.

If the infusion site becomes inflamed, replace the set and use a new site until the first site has healed.

Warnings (continued)

Replace the Quick-set if the tape becomes loose, because the soft cannula may be halfway out or dislodged.

If you are infusing insulin, do not change your infusion set just prior to bedtime, unless blood sugar can be checked 1-3 hours after insertion.

Do not put disinfectants, perfumes, or deodorants on your infusion set, as these may affect the integrity of the set.

Never prime the set or attempt to free a clogged line while the infusion set is inserted. You may accidentally inject too much medication.

Do not re-insert the introducer needle into the infusion set. Re-insertion could cause tearing of the soft cannula which would result in unpredictable medication flow.

Never use the infusion set for more than 72 hours.

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Maintenance

Clean the Quick-serter with soapy water, using liquid detergent or other household soaps.

Disinfect the Quick-serter with a 9% bleach solution or 70% isopropyl alcohol.

Store your Quick-serter in the released position to maintain optimum product performance and life.

	Do Not Re-Use this Device
	Attention, See Instructions For Use
STERILE EO	Sterilized using Ethylene Oxide
REF	Reference/Model Number
	Date of Manufacture
LOT	Lot Number
	Open Here
	Use By

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The Quick-set is made for MiniMed by:
Maersk Medical A/S, DK-4000, Roskilde, Denmark.
The Quick-serter is made by:
MiniMed Inc., Northridge, CA
24-Hour Helpline:
800-826-2099 or
818-576-5555
MiniMed
USA: Northridge, CA
+1-818-576-5555
EUROPE: MiniMed S.A. France
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