

# SECTION 5: BILLING AND REIMBURSEMENT GUIDELINES

## of the Professional Provider Office Manual

### 5.14 DURABLE MEDICAL EQUIPMENT HOME MEDICAL EQUIPMENT

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This is a subsection of Section 5: Billing and Reimbursement Guidelines of the *Professional Provider Office Manual*. If we make any procedural changes, in our ongoing efforts to improve our service to you, we will update the information in this subsection and notify our network providers. For complete *Professional Provider Office Manual* information, please refer to the other sections of this manual. Contact information for all manual sections is available in the Manual Reference Section.

For member eligibility, benefits or claims status information, we encourage you to use iLinkBlue ([www.BCBSLA.com/ilinkblue](http://www.BCBSLA.com/ilinkblue)), our online self-service provider tool. Additional provider resources are available on our Provider page at [www.BCBSLA.com/providers](http://www.BCBSLA.com/providers).

This manual is provided for informational purposes only and is an extension of your Professional Provider Agreement. You should always directly verify member benefits prior to performing services. Every effort has been made to print accurate, current information. Errors or omissions, if any, are inadvertent. The Member Contract/Certificate contains information on benefits, limitations and exclusions, and managed care benefit requirements. It also may limit the number of days, visits or dollar amounts to be reimbursed.

As stated in your agreement: This manual is intended to set forth in detail Blue Cross policies. Blue Cross retains the right to add to, delete from and otherwise modify the *Professional Provider Office Manual* as needed. This manual and other information and materials provided by Blue Cross are proprietary and confidential and may constitute trade secrets of Blue Cross.

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## DURABLE MEDICAL EQUIPMENT (DME)/HOME MEDICAL EQUIPMENT (HME)

Durable medical equipment/home medical equipment (DME/HME) refers to items that are used to serve a specific therapeutic purpose in the treatment of an illness or injury, can withstand repeated use, are generally not useful to a person in the absence of illness, injury or disease, and appropriate for use in the member's home.

### General Guidelines

Prior to submitting claims, there must be a valid, detailed physician order on file.

DME/HME claims must be filed to the Blue Plan where the equipment is shipped to or purchased at a retail store. The ordering provider's NPI must be included on the claim or it will be returned requesting that the claim be refilled with the ordering provider's NPI number.

#### Electronic Claims Requirements:

837 Professional Electronic Submission:

- The patient address is populated in 2010CA loop
- The NPI of the ordering provider is populated in 2420E loop
- The POS of the member is populated in 2300 loop, CLM05-01
- The service facility location is populated in 2310C loop

#### Paper Claim Requirements:

CMS-1500 Health Insurance Claim Form:

- The patient address where the DME/HME was shipped to in Block 5
- The NPI of the ordering provider in Block 17B - NPI of referring provider or other source
- The place of service (POS) in Block 24B (this represents where the item is actually being used - not where dispensed)
- The service facility location in Block 32 (for retail store information or location other than the patient address)

If you are a DME/HME supplier that is not located in Louisiana, you must be a participating provider for the member's plan, in the state (Louisiana) where the equipment or supply is shipped or purchased in a retail setting in order for the member to receive the highest level of member benefits. What does this mean to your office? If you are supplying DME/HME items to Blue Cross members residing in Louisiana, and you wish to receive payment directly and be identified in our provider directories, you may want to consider participating in our network. If you wish to inquire about participating in our networks, please contact Provider Contracting.

#### Scenario:

A DME/HME supplier in Mississippi receives and processes a request for DME/HME for a member in Louisiana. The equipment is then shipped to Louisiana for the member for pick up and/or purchase. The claim should be filed in Louisiana; the service area where the equipment is received/purchased.

### If You Order DME/HME

If you refer your patients to a DME/HME supplier that is not in Louisiana, the out-of-state DME/HME supplier must be a participating provider for the member's plan in the state (Louisiana) where the equipment or supply is shipped or purchased in a retail setting in order for the member to receive the highest level of benefits. What does this mean to your office? If you are writing an order for DME/HME for your patient, please refer them to a participating DME/HME supplier for the state in which your patient's equipment/supplies will be delivered to and provide your NPI so that it may be included appropriately when the DME/HME supplier files a claim for the requested supplies. Please help us ensure our members—your patients—receive the highest level of benefits available. Repeated use of a non-participating DME/HME supplier could subject you to a lower allowable charge.

### Authorization

Authorization requirements are defined based on the member's (subscriber's) contract benefits. Authorization is performed prior to services being rendered. When a claim is submitted for medical necessity, DME certification is required after the services are rendered or equipment is received. PPO does not require authorization; however, authorization is required for HMO. Please research iLinkBlue prior to any service provided to fully understand benefits, authorization requirements, limitations and exclusions for your patient. For contact information regarding authorizations, please see the Quick Reference Guide of this manual.

For certain DME, a recertification to determine medical necessity of continued use may be required after the equipment has been rented for a specified number of months (such as SIDS Apnea Monitor). It is the member's responsibility to ensure recertification takes place. The member and the participating DME supplier will be notified of the recertification requirements when the initial length of rental is approved. Any claims received beyond this approved period without a recertification of medical necessity will not be covered. DME certification forms are available by calling the Customer Care Center.

### DME Notification Letter

All initial and recertified DME claims will be reviewed by Blue Cross to determine medical necessity and DME coverage status. Once the review is completed, a DME notification letter is mailed to the member with a copy to the participating DME supplier.

The DME notification letter will provide one of the following:

- Approval of rental for a specified number of months (including recertification requirements)
- Approval of rental up to purchase allowance
- Approval of purchase
- Denial of rental or purchase

The DME notification letter does not guarantee payment of benefits. It only confirms approval/denial of the medical necessity of the DME. Benefit payment is always subject to the terms of the member contract.

### DME Accreditation Requirement

Blue Cross requires all new DME providers be accredited by the appropriate accrediting body as a condition of network participation. All existing DME providers must remain accredited by one of the following accrediting bodies to continue participation in the Blue Cross networks:

- Accreditation Commission for HealthCare, Inc. (ACHC)
- American Board for Certification in Orthotics & Prosthetics, Inc.
- Board of Certification/Accreditation International
- Commission on Accreditation of Rehabilitation Facilities (CARF)
- Community Health Accreditation Program (CHAP)
- HealthCare Quality Association on Accreditation (HQAA)
- National Association of Boards of Pharmacy (NABP)
- The Compliance Team, Inc.
- The Joint Commission
- The National Board of Accreditation for Orthotic Suppliers

Blue Cross will review each provider's accreditation status during the provider's regularly scheduled recertification cycle. Providers are recertified by Blue Cross every three years in accordance with URAC standards. Providers who do not maintain the required accreditation, or do not abide by Blue Cross' credentialing guidelines, will be subject to termination from any networks in which they participate.

Proof of accreditation must be sent to Network Administration.

### DME Benefits

Benefits for DME are provided in accordance with the benefit provisions of each specific member's benefit plan. Benefits will be provided if the DME is covered by the member's benefit plan and the prescribed equipment meets our DME and medical necessity requirements. Most member benefit plans provide for the rental of DME not to exceed the purchase allowance.

### Deductible, Coinsurance, Copay and Non-covered Services

After the member's deductible has been met, Blue Cross will pay a specified benefit for the remaining rental or purchase allowance for covered DME. The deductible and benefit amounts will vary according to the member's contract.

The member is responsible for payment of any deductible, coinsurance and non-covered services. However, the DME provider cannot bill the member for any amount that exceeds the Blue Cross allowable charge for rented or purchased DME pursuant to your contractual agreement with Blue Cross. Sales tax on DME is considered a non-covered charge and the member's responsibility according to most Blue Cross and HMO Louisiana member benefit plans.

**Please note:** for payment policies regarding DME considered a luxury item, see the Deluxe/Luxury Billing Guidelines of this manual section.

### Payment Allowance

Benefit payment for the rental of DME is based on the Blue Cross monthly rental allowance (not to exceed the purchase allowance). Benefit payment for the purchase of DME is based on the Blue Cross purchase allowance.

Rented DME is considered purchased once the monthly rental allowance equals the purchase allowance. The patient then owns the DME and neither the member nor Blue Cross can be billed for additional rental or purchase of the equipment.

### Rental vs. Purchase

Blue Cross has the option of approving either rental or purchase of DME. Based on medical necessity, rental may be approved for a specified number of months, rental may be approved up to the purchase allowance, or purchase may be approved.

### Billing Guidelines

DME must be billed using the most appropriate HCPCS code and appropriate modifiers in effect for the date of service. Claims billed with an inappropriate code/modifier combination will be returned to the Provider for submission of a corrected claim and will cause a delay of reimbursement.

#### Purchase

For purchased items, the appropriate HCPCS code must be billed with NU Modifier. See specific guidelines for insulin infusion pump and ventilator billing and modifiers.

#### Rentals

##### Daily Rental Codes

E0202 - PHOTOTHERAPY LIGHT WITH PHOTOMETER

E0935 - CONT PSV MOT EXER DEVC KNEE ONLY

E0936 - CONT PASS MOTION EXER DEVC NOT KNEE

Miscellaneous, unlisted, non-specific and not otherwise classified (NOC) codes should only be used when a more specific CPT or HCPCS code is not available. Components of the primary equipment should be billed with the most specific CPT or HCPCS code or the most specific unlisted or miscellaneous code. DME billed with unlisted, miscellaneous, non-specific and NOC codes must be billed with the name of the manufacturer, product number and quantity.

Codes for DME, medical supplies, orthotics, and prosthetics without an established allowable may require submission of the manufacturer name, product name, product number and quantity.

Charges for rental equipment accessories should be included in the rental price of the equipment with no separate or itemized billing when submitting claims for consideration to Blue Cross. All DME requests for special or customized features should be submitted to the Blue Cross Medical Review Department for prior approval using the Medical Certification Form.

All DME/HME claims for supplies that exceed the usual and customary utilization may result in a request for medical records to determine medical necessity.

All supplies must be requested by an eligible member or caregiver. Supplies are not to be automatically dispensed on a predetermined regular basis.

### Monthly Rentals

One unit should be billed for each month the item is rented, with the exception of the daily rental codes above. The maximum allowable for the rental is for a whole month. A "calendar month" is the period of duration from a day of one month to the corresponding day of the next month and is determined based on the "From" date reported on the claim. If a code is submitted with Modifier RR with units greater than 1, or multiple times during the same calendar month, Blue Cross and Blue Shield of Louisiana will only reimburse one monthly rate per calendar month to the provider except for daily rental codes as noted below.

Providers must use Modifier UE (used DME) when billing for used equipment. Used equipment will be reimbursed at a 25% discount.

### **Deluxe/Luxury and Special Features**

Certain DME is considered "deluxe" equipment due to its mechanical or electrical feature(s). For example, electric hospital beds are considered to be deluxe equipment. Deluxe equipment is covered only if Blue Cross determines that the deluxe equipment is both medically necessary and therapeutic in nature. Deluxe equipment ordered primarily for the member's comfort and convenience and determined to be not medically necessary and therapeutic will not be paid.

When the member requests deluxe equipment, and the medical necessity for the deluxe feature(s) of covered DME is not documented, benefits will be based on the rental or purchase allowance for standard/economical equipment.

A DME provider may deliver deluxe/luxury items as long as they could provide a standard product and the member or her/his representative has specifically requested the excessive or deluxe items or services with knowledge of the amounts to be charged. An Advance Beneficiary Notification (ABN) is required as documentation that the member has made such an informed request. If the ABN has been obtained, the DME/HME item would be submitted to Blue Cross with a Modifier GA appended as informational. The member is financially responsible for the difference in the billed charge for the standard equipment and the billed charge for the deluxe equipment, and is not to be held financially responsible for the discounted amount agreed to in your provider contract.

The charge to the member for the difference should be calculated based on the following example:

DME offers a standard item at \$500 and a deluxe item at \$800. The Blue Cross allowable is \$375. The member's additional out of pocket cost is \$300 (\$800-\$500) plus any deductible, coinsurance or copayment on the \$375 standard item Blue Cross allowable.

Due to certain conditions, illnesses or injuries, medical necessity may require DME with special or customized features. All equipment of this type is subject to individual payment consideration and prior approval of Blue Cross.

Charges for rental equipment accessories should be included in the rental price of the equipment with no separate or itemized billing when submitting claims for consideration to Blue Cross. All DME requests for special or customized features should be submitted to the Blue Cross Medical Review Department for prior approval using the Medical Certification Form.

### Breast Pumps

Blue Cross provides the DME benefits for the purchase of a breast pump per pregnancy. Some benefit plans provide coverage at 100% of the allowable charge for a standard manual pump (E0602). However, for these plans unless prior authorized for medical necessity, a hospital-grade breast pump (E0604) is considered a deluxe/luxury item with the member being responsible for any amount above the allowable charge (please refer to the special instructions for deluxe/luxury items).

Accessories and/or replacement parts (A4281-A4286) necessary for the effective functioning of covered DME are considered an integral part of the rental and/or purchase allowance and will not be covered separately. In addition, the provider shall provide at minimum, a one-year warranty for rental and/or purchase of DME.

### CPAP Supplies

CPAP supplies will be limited as follows:

Code	Units/Month
A4604	1 per 3 months
A7027	1 per 3 months
A7028	6 per 3 months or 2 per month
A7029	6 per 3 months or 2 per month
A7030	1 per 3 months
A7031	3 per 3 months or 1 per month
A7032	6 per 3 months or 2 per month
A7033	6 per 3 months or 2 per month
A7034	1 per 3 months
A7035	1 per 6 months
A7036	1 per 6 months
A7037	1 per 3 months
A7038	6 per 3 months or 2 per month
A7039	1 per 6 months
A7046	1 per 6 months

## Hearing Aids

To ensure that your hearing aid claims are processed as quickly as possible, please follow these guidelines:

- Patient must receive medical clearance and a medically appropriate audiological evaluation from a physician.
- Hearing aids must be fitted and dispensed by a licensed audiologist or licensed hearing aid specialist following the physician's medical clearance.
- Dispensing fees should be billed globally with the hearing aid charge. Dispensing fees are not payable when billed separately.
- Hearing aid claims should be filed with the appropriate Modifier LT or RT if only billing for one ear. Because binaural means both ears, it is not appropriate to bill Modifier LT and/or RT for codes with "binaural" in the description. The fee on codes for binaural hearing aids is for both ears.

Always verify member benefits and eligibility prior to rendering services. Member benefits are available anytime on iLinkBlue.

## Infusion Pumps

In an effort to appropriately align reimbursement to the types and cost of equipment provided, modifier(s) are required on infusion pump codes E0784 and E0787. These items are for purchase only.

- For **Omnipod** pumps, bill code E0784 and Modifier NU in the first position.
- For **Medtronic** pumps (not closed-loop), bill code E0784 and Modifier SC in the first position and NU in the second position.
- For Tandem pumps (not closed-loop), bill code E0784 and Modifier JB in the first position and NU in the second position.
- For **Tandem** closed-loop pumps, bill code E0787 and Modifier JB in the first position and NU in the second position.
- For Medtronic closed-loop pumps, bill code E0787 and Modifier SC in the first position and NU in the second position.
- For pumps other than Omnipod, Medtronics or Tandem, bill Modifier KD in the first position and NU in the second position.

Coding Examples for Infusion Pumps:

- E0784NU – Omnipod infusion pump purchase
- E0784SCNU – Medtronic (not closed-loop) infusion pump purchase
- E0787JBNU – Tandem (closed-loop) infusion pump purchase
- E0784KDNU – Infusion pump purchase **other than** Omnipod, Medtronics or Tandem brand/model



## Orthotics

Evaluation, measurement and/or casting and fitting of the orthosis are included in the allowance for the orthosis and are not separately billable.

Repairs to an orthosis are billable when they are necessary to make the orthosis functional. The reason for the repair must be documented in the supplier's record. If the expense for repairs is greater than providing another entire orthosis, no payment will be made for the amount in excess.

Replacement of a complete orthosis or component is billable if medically necessary.

Labor for replacing an orthosis component that is coded with a specific "L" HCPCS code is included in the allowance for that component.

Billable orthosis components and labor must be billed on the same claim form.

## Oxygen Equipment

Reimbursement for stationary and portable oxygen equipment will be based on a five-year Reasonable Useful Lifetime (RUL) of the equipment. Oxygen equipment may be purchased or rented. If oxygen equipment is rented, monthly rental payments to the supplier will be limited to 36 months; however, the supplier responsibilities will extend for the RUL (60 months) of the equipment.

A new 36-month rental period may only begin if the item is irreparably damaged (fire, flood, etc.) or the item is lost or stolen. Normal wear and tear, malfunction, repair and/or routine maintenance will not begin a new rental period.

### 1-36 Months:

The monthly rental fee for stationary oxygen equipment (E0424, E0439, E1390, E1391) includes: stationary contents, portable contents, accessories and maintenance. If the member does not have a stationary system and rents or owns only a portable system, separate reimbursement for oxygen contents will be allowed for the portable system.

However, if stationary equipment is subsequently added, separate payment for portable contents ends since payment for portable contents is included in the stationary equipment monthly rental fee.

	Concentrator	Gaseous\Liquid Oxygen System
Stationary Monthly Payment	Yes	Yes
Oxygen Contents Fee	N/A	No
Accessories	No	No
Portable Monthly Payment	Yes	Yes
Portable Contents Fee	No	No

### Supplier Responsibilities:

- The same supplier should provide both the stationary and portable equipment as needed. The member should not receive the stationary equipment from one provider and the portable equipment from a different provider.
- The supplier who provides oxygen equipment for the first month must continue to provide oxygen equipment, accessories, maintenance and contents through the 36-month rental period with the following exceptions:
  - a. The member relocates outside of the supplier's area (this will not start a new 36-month rental period).
  - b. The member chooses to obtain oxygen from a different supplier (this will not start a new 36-month rental period).
- The supplier cannot provide different types of oxygen equipment/modalities unless the following criteria are met:
  - a. The physician orders different equipment (this will not start a new 36-month rental period).
  - b. The member chooses to receive an upgrade (this will not start a new 36-month rental period).

### 37-60 Months:

There are no further monthly rental payments for oxygen equipment during months 37-60 of the five-year RUL of the oxygen equipment. If the portable equipment rental (E0431, E0433, E0434, E1392, K0738) began after the use of the stationary equipment began, then the reimbursement for the portable equipment may continue until 36 rental payments have been made for the portable system.

Reimbursement for stationary (E0441 or E0442) or portable (E0443 or E0444) oxygen contents begins when the rental for the stationary equipment ends. A supplier may bill on a monthly basis for oxygen contents, but no more than one unit of service for portable contents and one unit of service for stationary contents may be billed per month.

There is no separate reimbursement for accessories; however, maintenance may be reimbursed separately. Maintenance and servicing charges may be billed using HCPCS code K0740 for concentrators. This may be billed every six months beginning no sooner than six months following the end of the 36-month rental period.

If the beneficiary has a stationary concentrator, portable liquid equipment and a stationary liquid tank to fill the portable cylinders, when payment for contents begins, payment will only be made for portable liquid contents.

	Concentrator	Gaseous\Liquid Oxygen System
Stationary Monthly Payment	No	No
Oxygen Contents Fee	N/A	Yes
Accessories	No	No
Portable Monthly Payment	No	No
Portable Contents Fee	Yes	Yes

#### Supplier Responsibilities:

- The supplier is required to provide equipment, accessories, maintenance and contents for the remainder of the five-year RUL of the stationary equipment. The equipment and accessories should be provided without billing Blue Cross or the member.
- Criterion for providing different equipment/modalities is the same in months 37-60 as they are in the initial 36 months.

#### Months 61 And After:

- The supplier can begin a new 36-month rental period if replacement equipment is issued to the member.
- If the supplier chooses to discontinue service, then the member must find a new oxygen supplier and begin a new 36-month rental period.
- The supplier can continue supplying the current equipment without replacing it. Contents for portable oxygen equipment and maintenance for concentrators will be reimbursed the same as months 37-60.

#### Purchased Equipment:

If a member chooses to purchase oxygen equipment, the contents, accessories and maintenance will be reimbursed separately.

	Concentrator	Gaseous\Liquid Oxygen System
Stationary Monthly Payment	N/A	N/A
Oxygen Contents Fee	N/A	Yes
Accessories	Yes	Yes
Portable Monthly Payment	N/A	N/A
Portable Contents Fee	Yes	Yes

#### Prosthetics

The following items are not separately billable and are included in the reimbursement for a prosthesis:

- Evaluation of the residual limb and gain
- Cost of component parts and labor contained in the HCPCS codes
- Fitting of the prosthesis to include adjustments of the prosthesis or prosthetic component
- Routine periodic servicing to include testing, cleaning and checking of the prosthesis

### Repair or Maintenance other than Prosthetic and Orthotic DME

The repair or maintenance of rented DME/HME is the responsibility of the participating DME/HME supplier at no additional charge to the member. Rental rates include reimbursement for repair, adjustment, maintenance and replacement of equipment and its components related to normal wear and tear, defects or aging. If the expense for repairs is greater than the estimated expense of purchasing another entire item, no payments can be made for the amount of the excess. Repairs to member-owned DME are billable using the appropriate code (K0739 or K0740) when necessary to make the item functional. For ventilators, see section on the next page.

For facial prostheses codes L8040 thru L8047, providers must bill using Modifiers KM or KN when the prosthesis is being replaced.

- KM replacement of facial prosthesis including new impression/moulage
- KN replacement of facial prosthesis using previous master model

### TENS Units and Supplies

Refer to the below chart when filing claims for transcutaneous electrical nerve stimulation (TENS) units and supplies. Payment for the codes listed is not guaranteed. Coverage is subject to the member's contract.

TENS Unit Codes	Code Description	Frequency	Billing/Reimbursement Guidelines
E0720	TENS 2 lead unit	<ul style="list-style-type: none"> <li>• Rental - one per month</li> <li>• Purchased - determined by member's benefit</li> </ul>	<ul style="list-style-type: none"> <li>• Supplies for the unit are included in the rental allowance.</li> <li>• When purchased, supplies are included in the allowance for the first month of purchase.</li> </ul>
E0730	TENS 4 lead unit	<ul style="list-style-type: none"> <li>• Rental - one per month</li> <li>• Purchased - determined by member's benefit</li> </ul>	<ul style="list-style-type: none"> <li>• Supplies for the unit are included in the rental allowance.</li> <li>• When purchased, supplies are included in the allowance for the first month of purchase.</li> </ul>
E0731	TENS Garment	N/A	Only covered with supporting documentation of medical necessity.
A4557	Lead wires	1 annually	Replacement of lead wires will be covered when they are inoperative due to damage and the TENS unit is still medically necessary.
A4595	Electrical stimulator supplies, 2 lead, per month	1 or 2 units - monthly	Purchased units only: <ul style="list-style-type: none"> <li>• 1 unit per month for 2 lead</li> <li>• 2 units per month for 4 lead</li> </ul>

Other supplies including but not limited to the following, will NOT be separately allowed:

- A4245 - alcohol wipes
- A4556 - replacement electrodes
- A4558 - conductive paste or gel
- A4630 - replacement batteries
- Battery charger used with a TENS unit

### Ventilators

Ventilator HCPCS codes E0465 (home ventilator, any type, used with invasive interface), E0466 (home ventilator, any type, used with non-invasive interface), and E0467 (home ventilator, multi-function) are to be billed and reimbursed as rental using the Modifier RR, which includes maintenance and accessories. One unit will represent one calendar month of rental. Also, one additional rental rate at 50% (upon prior authorization) will be allowed in the same calendar month for a backup ventilator reported with a rental modifier (RR) plus Modifier TW (backup equipment), appended to HCPCS code E0465, E0466 or E0467.

### Wheelchairs (customized)

Please follow the billing guidelines below when you bill Blue Cross for **customized** wheelchairs:

File the entire customized wheelchair claim using HCPCS code E1220 and we will reimburse the entire claim at manufacturer's suggested retail price (MSRP) minus 25% discount of charges. These claims require detailed invoices to be submitted. To expedite this process, please submit hardcopy paper claims and supporting documents.

- Evaluation and setup fees will not be reimbursed separately.
- Use K0739 to bill for equipment maintenance that is not covered under the warranty.
- Reimbursement will be based on the allowable charge.

### Wheelchairs (non-customized)

Wheelchair accessories must be billed on the same claim form as the wheelchair itself. Multiple accessories using code K0108 should each be billed on a separate line.

For purchased DME/HME, the participating DME/HME supplier must provide a one-year warranty agreement to the member. The participating DME/HME supplier must always inform the member about any DME/HME warranty provided by the manufacturer.

The DME/HME supplier agrees to provide all DME/HME services and supplies and orthotic and prosthetic devices, if applicable, according to the following standards:

- Free delivery
- Free installation
- Seven day-a-week, 24-hour emergency services by both technicians and professionals
- Rental equipment repair and maintenance service (same day service, if required)
- Clinical professionals for patient education and home management, and, where necessary, written graphically-illustrated patient education and instruction manuals
- Availability of standard/economical models that meet the patient's needs and quality standards