CLINIC VISIT

Clinical Study of IPPB

Form [7][1][7][1] 1-4

Date of clinic visit [ ][ ][ ] Mo Day Yr 5-10

A. PATIENT IDENTIFICATION

1. Treatment center number [ ] 11
2. Patient number [ ][ ][ ][ ] 12-15
3. Date of birth [ ][ ][ ] Mo Day Yr 16-21

B. VISIT INFORMATION

1. Month number (1-36) [ ][ ] 22-23

	NO	YES	
2. Was this visit missed? *If YES, complete Sections A-C only of this form and Form 724 (Missed Visit)*	[1]	[2]	30
3. Was this visit completed within the time period specified in the patient's appointment schedule?	[1]	[2]	31

If NO, why not _____

C. DATA FROM HOME VISITS (Form 716) *(Information requested pertains to the interval since the last home visit or clinic visit; of if missed, during the last month.)*

	Visit #1 (Month 1,4,7,10...)		Visit #2 (Month 2,5,8,11...)	
1. Date of visit *(99 99 99 if none)*	[ ][ ][ ] Mo Day Yr	32-37	[ ][ ][ ] Mo Day Yr	38-43
2. Month number (1-36)	[ ][ ]	44-45	[ ][ ]	46-47
3. How many cigarettes does the patient smoke per day? *(99 only if unknown)* [C6 on Form 716]	[ ][ ] /day	48-49	[ ][ ] /day	50-51
4. Rating of patient's physical condition *(1-7)* [E4]	[ ]	52	[ ]	53
5. Breathing frequency while taking treatment (breaths/minute) [F1]	[ ][ ]	54-55	[ ][ ]	56-57
6. Tidal volume patient is using for treatments (ml) [F2]	[ ][ ][ ][ ]	58-61	[ ][ ][ ][ ]	62-65
7. Cumulative meter reading [F3]	0 [ ][ ][ ][ ][/]	66-70	0 [ ][ ][ ][ ][/]	71-75
8. Serial # of machine [F4]	[ ][ ][ ][ ][ ][ ][ ]	76-82	[ ][ ][ ][ ][ ][ ][ ]	83-89
	NO YES		NO YES	
9. Has the machine been functioning properly? [F5] Comment if NO _____	[1] [2]	90	[1] [2]	91
10. Has the machine been replaced since the last visit? [F6] *If YES, submit Form 725.*	[1] [2]	92	[1] [2]	93

	Visit #1 (Month 1,4,7,10...)		Visit #2 (Month 2,5,8,11...)	
11. Number of theophylline pills prescribed per day *(0 if none)* [G1]	☐☐	94-95	☐☐	96-97
12. Number of theophylline pills used this month *(999 if unknown)* [G2]	☐☐☐	98-100	☐☐☐	101-103
13. Average number of times per day that the patient used the cartridge inhaler [G3]	☐	104	☐	105
14. Average number of times per day that the patient took machine delivered bronchodilator [G4]	☐	106	☐	107
Comment if <2 or >4 _____				
15. Average length of each IPPB or CN treatment (minutes) [G5] Comment if <10 or >20 _____	☐☐	108-109	☐☐	110-111
16. Number of days that the machine was not used at all [G6] Comment if >7 _____	☐☐	112-113	☐☐	114-115
17. Medication that patient is using in his machine [G7]				
Metaproterenol	1	116	1	117
Bronkosol	2		2	
Barotec	3		3	
Other _____	4		4	
18. Prescribed dose of Metaproterenol or other medication, per treatment (mg) [G8]	☐☐	118-119	☐☐	120-121
19. Prescribed amount of diluted medication used for each treatment (cc) [G9]	☐•☐	122-124	☐•☐	125-127
20. Amount of diluted medication used since last visit (cc) *(If medication is not premixed, record undiluted amount here _____ and the estimated diluted volume in the boxes.)* [G10]	☐☐☐	128-130	☐☐☐	131-133
	NO YES		NO YES	
21. Is the patient measuring the medication according to the study protocol? [G11]	1 2	134	1 2	135
22. Has the patient been cleaning and storing the machine properly? [G12]	1 2	136	1 2	137
23. Has the patient been taking his treatments properly [G13]	1 2	138	1 2	139

Comment if any of questions 21, 22 or 23 are answered NO _____

Patient #_____ Date _____

D. SYMPTOM HISTORY (over the last month).
The patient should be given the written questionnaire. The answers are to be recorded here.

	None	Mild	Mod.	Sev.	
1. Cough	1	2	3	4	150
2. Sputum	1	2	3	4	151
3. Shortness of breath	1	2	3	4	152
4. Wheezing	1	2	3	4	153
5. Fluid retention	1	2	3	4	154

6. How many cigarettes does the patient usually smoke per day? *(99 only if unknown)* ☐☐ 155-156

E. PHYSICAL EXAMINATION

1. Blood pressure *(with patient sitting)* (mmHg)
   Systolic ☐☐☐ 160-162
   Diastolic ☐☐☐ 163-165

2. Respiratory rate/min ☐☐ 166-167

3. Apical heart rate/min ☐☐☐ 168-170

Pulmonary	NO	YES	
4. Does the patient use the accessory neck muscles (scalene and/or sterno-cleidomastoid) for quiet breathing?	1	2	171
5. Does the patient have rales?	1	2	172
If YES, are they localized?	1	2	173
6. Does the patient have wheezes on quiet breathing?	1	2	174
If YES, are they localized?	1	2	175
7. Does the patient have decreased breath sounds?	1	2	176
Cardiac			
8. Does the patient have increased jugular venous pressure?	1	2	177
9. Does the patient have a gallop rhythm (S_3 or S_4)?	1	2	178
10. Is the rhythm regular?	1	2	179

Other	NO	YES		
11. Does the patient have hepatomegaly?	1	2	180	180
12. Does the patient have peripheral edema?	1	2	181	81

F. HISTORY

1. Has there been any change in the patient's employment status since the last quarterly evaluation? *(check only one)*

No change	1	185	85
Became employed	2		
Retired	3		
Became disabled	4		
Other change	5		

If YES, specify _____

_____

2. How many times has the patient been hospitalized since the last quarterly evaluation? *(0 if none) (Form 720 should be completed for each hospitalization.)* ☐ 186

If YES, give the reason(s) _____

_____

Hospital _____

Dates _____

3. How many other treated acute exacerbations has the patient experienced since the last quarterly evaluation? *(Form 727 should be completed for each exacerbation.)* ☐ 187

4. Since the last quarterly evaluation has the patient experienced any of the following conditions? (based on extra clinic visits or hospitalizations)

	NO	YES	
a. Worsening airway obstruction with infection	1	2	188
b. Worsening airway obstruction without infection	1	2	189
c. Pneumonia	1	2	190
d. Acute myocardial infarction	1	2	191
e. Left ventricular failure	1	2	192

Patient #_____ Date _____

	NO	YES	
f. Right ventricular failure	1	2	193
g. Pneumothorax	1	2	194
h. Pulmonary embolism	1	2	195
i. Arrhythmia: Atrial	1	2	196
j. Arrhythmia: Ventricular	1	2	197
k. Other: _____	1	2	198
5. Does the patient meet the criteria for oxygen administration?	1	2	199
6. Is the patient receiving supplemental oxygen?	1	2	200
a. If YES, date started (Mo Day Yr)			201-206
b. If YES, average number of hours per day			207-208
c. If YES, average flow (liters per minute)			209

	NO	YES	
7. Has the patient received any other medical attention since the last quarterly evaluation?	1	2	210

If YES, specify problem

_____

_____

8. Based on all the information obtained from this examination, rate your perception of the change in the patients physical condition since the last home visit *(enter number in box).* 211

No change

Greatly improved 1 2 3 4 5 6 7 Greatly deteriorated

	NO	YES	
9. Will Form 721 be completed? *(Form 721 should be completed instead of Forms 710 or 715 if the patient is having an acute exacerbation at this time or has remained stable for less than 2 weeks following a hospitalized exacerbation.)*	1	2	212

10. How much alcohol does the patient usually drink per week? *(1 unit = 1 beer or 1 glass of wine or 1 shot of liquor)* ___ # 213-214

G. COMPLIANCE WITH TREATMENT REGIMENS

1. Number of theophylline pills prescribed per day *(0 if none)* ___ # 220-221
2. Number of theophylline pills used this month ___ # 222-224
3. Average number of times per day that the patient used the cartridge inhaler ___ # 225
4. Average number of times per day that the patient took machine delivered bronchodilator. Comment if <2 or >4 _____ ___ # 226

_____

5. Average length of each IPPB or CN treatment (minutes). Comment if <10 or >20 _____ ___ # 227-228

_____

6. Number of days in the past month that the machine was not used at all. Comment if >7 ___ # 229-230

_____

_____

7. Medication that patient is using in his machine

Metaproterenol	1	231
Bronkosol	2	
Barotec	3	
Other _____	4	

8. Prescribed dose of Metaproterenol or other medication, per treatment (mg) ___ # 232-233
9. Amount of diluted medication used for each treatment (cc) ___ . ___ # 234-236
10. Amount of diluted medication used since last visit (cc) *(If medication is not premixed, record undiluted amount here _____ and the estimated diluted volume in the boxes.)* ___ # 237-239

	NO	YES	
11. Has the patient been cleaning, storing and using the machine properly? Comment if NO _____	1	2	240
12. Has the machine been functioning properly? Comment if NO _____	1	2	241
13. Has the machine been replaced since the last home visit? *(If YES, submit Form 725.)*	1	2	242

H. THERAPIES USED BY THE PATIENT DURING THE PAST MONTH *(Ask the patient about each type)*

	NO	YES	
1. Metaproterenol inhaler	1	2	250
2. Other cartridge inhaler	1	2	251
3. Oral theophylline	1	2	252
4. Other oral bronchodilator	1	2	253
5. Antibiotics	1	2	254
6. Oral corticosteroids	1	2	255
7. Inhaled corticosteroids	1	2	256
8. Digoxin	1	2	257
9. Diuretic	1	2	258
10. Expectorant	1	2	259
11. Cough syrup	1	2	260
12. Vaporizer	1	2	261
13. Other - 1	1	2	262
14. Other - 2	1	2	263
15. Chest physiotherapy	1	2	264

Comments: _____

_____

_____

_____

_____

_____

16. Type of oral theophylline *(See code list, blank if not prescribed).* ☐☐ 265-266

17. Mg. of theophylline prescribed per day *(Blank if not prescribed).* ☐☐☐ 267-269

I. THEOPHYLLINE LEVEL

	NO	YES		
1. Is the patient taking theophylline? *(If NO, SKIP to Section J)*	1	2	280	0
2. Did the patient have theophylline level blood sample drawn since the last clinic visit? *(to be done 5th, 9th, 15th, 17th, and 29th months) (If NO, SKIP to Section J)*	1	2	281	1
3. Was this blood sample drawn at the clinic?	1	2	282	2
4. Month number of visit at which sample was drawn.	☐☐		283-284	
*5. Number of hours between time patient last took theophylline pills and blood sample drawn.	☐☐		285-286	
*6. Number of mg. of theophylline taken.	☐☐☐		287-289	
7. Theophylline level (µg/ml)	☐☐		290-291	91

J. HEMATOCRIT AND HEMOGLOBIN

	NO	YES	
1. Did the patient have these performed this clinic visit? *(to be done 12th, 24th, and 36th months)*	1	2	292
2. Hct (%)	☐☐		293-294
3. Hgb (gm/dl)	☐☐☐		295-297

K. Person responsible for the information recorded on this form:

_____ Date _____

*If ... drawn at home, information is from Form 716.1, Section H.